Award Number:  W81XWH-12-1-0549

TITLE: Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

PRINCIPAL INVESTIGATOR:  Christopher P. Smith, MD

CONTRACTING ORGANIZATION:  Baylor College of Medicine, Houston, TX 77030

REPORT DATE: October 2014

TYPE OF REPORT: Annual

PREPARED FOR:  U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland  21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

Christopher P. Smith, MD

E-Mail: cps@bcm.edu

Baylor College of Medicine
One Baylor Plaza, T100
Houston, TX 77030-3498

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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No subjects have been treated as yet. Recruitment at Michael E. DeBakey VAMC has been difficult due to eligibility criteria. Dr. Smith has completed the application to open patient recruitment to a new site with a large spinal cord injury population, The Institute of Rehabilitation and Research (TIRR). He has just become credentialed and the IRB process will begin immediately. Enrollment will begin as quickly as possible.

Botulinum Toxin, Oxybutynin, Overactive Bladder, Spinal Cord Injury, Urinary Incontinence, Nerve Growth Factor, Urine Biomarkers

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<td>- IRB renewal submission: 03/03/14</td>
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<td>- OAB-Patient Satisfaction with Treatment Questionnaire (OAB_PSTQ)</td>
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<td>- Patient Global Assessment (PGA)</td>
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<td>- Diaries</td>
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<td>- Pill</td>
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INTRODUCTION

This is a Phase 3B, double-blind, randomized, placebo-controlled, parallel-group study to assess the safety and efficacy of onaBoNT-A or 15 mg per day of oral oxybutynin hydrochloride ER in 36 spinal cord injured veterans who visit the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) in Houston, TX and are diagnosed with neurogenic detrusor overactivity. Volunteers will include both males and females who are 18 to 80 years of age. There are no eligibility restrictions as to race or ethnicity.

KEYWORDS

Botulinum Toxin, Oxybutynin, Overactive Bladder, Spinal Cord Injury, Urinary Incontinence, Nerve Growth Factor, Urine Biomarkers

OVERALL PROJECT SUMMARY

Previously, one patient was consented but did not respond to repeated attempts to contact him to set his screening visit appointment. He is considered lost to follow-up.

The protocol received continuing BCM IRB approval on April 10, 2014. An amendment to allow brochures to be distributed during the MEDVAMC Research Week was approved on April 21, 2014. An amendment to allow the use of the revised HIPAA Authorization form is undergoing IRB review that is scheduled for 10/22/14.

This past year, 130 charts were reviewed and discuss in SCI Rounds. Theses patient where not eligible for our study due to the following:

− 30 patients do not met Inclusion #6
− 22 patients do not met Inclusion #7
− 28 patients do not met Inclusion #10
− 20 patients do not met Inclusion #11
− 3 patients met Exclusion #1
− 1 patient Exclusion #2
− 1 patient chart states not interested in getting Botox
− 1 patient chart cannot tolerate Oxybutynin
− 1 patient chart says Botox did not work for this patient
− 1 patient chart says Oxybutynin causes patient to have difficulty swallowing
− 1 patient chart says he has behavior issues
− 3 patients were interested in study but they are non-veterans
− 18 patients’ charts indicate non-Texas residents
KEY RESEARCH ACCOMPLISHMENTS: Nothing to report

CONCLUSIONS

Dr. Smith has completed the application to open patient recruitment to a new site with a large spinal cord injury population, The Institute of Rehabilitation and Research (TIRR). He has just become credentialed and the IRB process will begin immediately. Enrollment will begin as quickly as possible.

PUBLICATIONS ABSTRACTS AND PRESENTATIONS: None

INVENTIONS, PATENTS AND LICENSES: None

REPORTABLE OUTCOMES: None

OTHER ACHIEVEMENTS: None

REFERENCES: None

APPENDICES

- IRB renewal submission: 03/03/14
- IRB Annual Approvals: 04/21/14
  - Letter
  - Informed Consent Document
- Questionnaires
  - Incontinence Quality of Life Instrument Neurogenic Module
  - Incontinence Quality of Life Instrument (I-QOL)
  - OAB-Patient Satisfaction with Treatment Questionnaire (OAB_PSTQ)
  - Patient Global Assessment (PGA)
- Diaries
  - Pill
  - Urine
- CV: 09-02-14

QUADCHART: Attached
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

RENEWAL

Protocol Number: H-26296
Principal Investigator: CHRISTOPHER PATRICK SMITH
Initial Submit Date: 05/24/2012
Renewal Submit Date: 03/03/2014
Protocol Title: A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER 11-09-10-04)

SUBJECTS
During your last approval period, you were approved to enroll 36 subjects locally and 36 subjects worldwide.

<table>
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<tr>
<th>Race/Ethnicity</th>
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<th>Female</th>
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<td>0</td>
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<tr>
<td>White</td>
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LOCAL: 1  
WORLDWIDE: 1

MONITORED
If the study was monitored during the last approval period, please indicate by whom and provide a brief description of the findings:
Not Applicable

PROTOCOL STATUS
If the study will not be open to recruitment during the next approval period, indicate why the study should remain open:
Not Applicable

NEW INFORMATION
I am aware of no new information that might effect a subject's willingness to continue participating in this study.

GENERAL SUMMARY
The subject was entered onto the master list of subjects for the study signed a consent form prior to undergoing any study interactions or interventions, unless the IRB has granted a waiver of consent or a waiver of documentation of consent. None of these subjects are considered members of vulnerable populations. We have not had any adverse events, unanticipated problems involving risks to subjects or others; therefore, there were no SAEs (whether related or unrelated to the research) reported to the IRB. A total of 1 subject has signed an informed consent document for this study. He has not responded to requests to make an appointment for the screening visit. A certified letter was mailed to him, but was not returned. The subject has been withdrawn from the study. Recruitment has been difficult for this population. Two hundred and fifty-seven (257) letters were mailed out to SCI patients that were previously seen in the VA clinics. Results: 11 called to discuss the study. Of those 11, 8 did not meet eligibility because 5 were not experiencing leakage, 2 had stress incontinence, and 1 patient did not have SCI at all. Of the 3 that qualified: 1 lived to far to be in this study, 1 declined to participate once the study was explained to wife, and 1 declined because he didn't want to CIC. 6 letters were returned due to outdated addresses with no forwarding addresses. One letter was received stating that the patient was deceased. Four patients responded to the flyers posted in the clinics. Results: 1 had total incontinence, 1 was planning to move to Louisiana but if he did not, he would call back in new year, and 1 is a cocaine user. 1) We are attending a weekly SCI Urology meeting to directly interact with PMR staff regarding potential study candidates. 2) We are also manually reviewing the entire SCI database to identify local patients we will then attempt to directly contact by phone to inquire about their interest in our study.

RISK/BENEFIT RATIO

**EVENTS**  
No Events have been reported.

**EXCEPTIONS**  
No Exceptions have been reported.

**DEVIATIONS**  
No Deviations have been reported.

**AMENDMENTS**  
(As of: 6/9/2014 10:08:51 AM)  
(Sort Order: Amendment Date)

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<tr>
<td>04/14/2014</td>
<td>Other Amendment</td>
<td>Approval of already approved brochure so it can be used at MEDVAMC Research Week. Section J2 reads, 'Brochures may be placed in the clinic area to help draw attention to the clinical research study.' It has been edited to include, 'The brochures will be used as posters during the MEDVAMC Research Week.'</td>
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<tr>
<td>11/20/2013</td>
<td>Multiple Amendments</td>
<td>1. Informed consent has been revised to remove unnecessary spaces and language. There appears to be a 'period' in the printed (or print view) that is not appropriate. We are not able to remove it. 2. The DOD has requested that the sentence regarding the study's sponsor by revised. This sentence is at the end of the Background section. 3. All advertising has been revised to indicate the study coordinator's new telephone number at the VA and replacing of the BCM logo.</td>
</tr>
<tr>
<td>11/01/2013</td>
<td>Other Amendment</td>
<td>Addition of PHI being collected in order to provide the subjects' stipends. Sections H, L and Q have been revised.</td>
</tr>
<tr>
<td>07/05/2013</td>
<td>Multiple Amendments</td>
<td>Protocol v. 6/12/13 Protocol Changes from 4-30-13 to 6-12-13 Purpose – page 15 Was: At baseline, each follow-up period, and after a two week washout period, urine will be collected for analysis of biomarkers for nerve growth factor (NGF) and chemokines/cytokines to determine the potential role of urine biomarkers as patient selection and surrogate endpoints of treatment outcome predictors. Now: At baseline and each follow-up period, urine will be collected for analysis of biomarkers for nerve growth factor (NGF) and chemokines/cytokines to determine the potential role of urine biomarkers as patient selection and surrogate endpoints of treatment outcome predictors. Clarification of detrusor overactivity: Eligibility – Inclusion #7, page 17 Was: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or Day 1 (prior to randomization, or if within 3 months of screening if patient is off antimuscarinic/anticholinergic drugs at the time of urodynamic testing). Now: Volunteer has detrusor overactivity (defined as a phasic rise in bladder pressure during the filling phase determined by urodynamics) demonstrated during the screening period or within 6 months of screening if patient is off antimuscarinic/anticholinergic drugs at the time of urodynamic testing). Recruitment Process, page 19 Advertising brochures will be placed in the Urology Clinic; included in the MEDVAMC newsletter; and included in a mail out planned for potential subjects. An advertisement will be placed on the Craig's List website. Study Procedures 10.1 Screening - Visit 1, page 19</td>
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Was: Urodynamic studies: Now: Urodynamic studies (if not performed 6 months prior to the Randomization Visit): 10.3 Post Randomization/Treatment Visits (Follow Up), page 23 Was: Post Randomization/Treatment Visits (Follow Up) (Day 3 (± 3 days) weeks, and 6, 9, 12, 18, 24, and 26 months post randomization/treatment) Now: Post Randomization/Treatment Visits (Follow Up) -Day 3, and Weeks 4, 12, and 24 (± 3 days) post randomization/treatment 10.3.2 Visit 4, page 23 Was: Visits 4, 5, and 7: Weeks 4, 8, and 16 (± 3 days) post randomization/treatment Now: Week 4 (± 3 days) post randomization/treatment 10.3.3. Visit 5, page 23 Was: Visit 6: Week 12 (± 3 days) post randomization/treatment Now: Visit 5: Week 12 (± 3 days) post randomization/treatment 10.3.4. Visit 8, page 23 Was: Visit 9 - End of Study Visit Now: End of Study Visit Was: Urodynamic studies no longer required at End of Study Visit Now: Urodynamic studies no longer required at End of Study Visit CMP (Complete Metabolic Panel) has been added. Data Analysis, page 24 Was: Additionally, we will look at the longitudinal pattern of the questionnaires at baseline, 4, 8 and 12 weeks…. Now: Additionally, we will look at the longitudinal pattern of the questionnaires at baseline, 4, and 12 weeks…. Subject Stipend Section 17: Withdrawal from Study, page 32 Was: Volunteers participating in this study will not receive any payment for their participation. Now: Volunteers participating in this study will receive $50 for completing each of the study visits 2, 4, 5, and 6. Schedule of Events: Appendix I, page 41 Advertising: BCM website revision, Brochure, Patient Letter, and Craig's List ad

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Was: Volunteers participating in this study will not receive any payment for their
participation. Now: Volunteers participating in this study will receive $50 for
completing each of the study visits 2, 4, 5, and 6.

**Amendment Submit Date:** 05/29/2013  
**Reason:** Multiple Amendments  
**Description:** Protocol v.4/30/13 changes: 1. Clarification of time frame for washout period for antimuscarinic/anticholinergic drugs: Eligibility – Inclusion #7, page 17
Was: Volunteer has detrusor overactivity (defined as a phasic rise in bladder
pressure during the filling phase determined by urodynamic testing) demonstrated
during the screening period or Day 1 (prior to randomization). Now: Volunteer
has detrusor overactivity (defined as a phasic rise in bladder pressure during
the filling phase determined by urodynamic testing) demonstrated during the
screening period or Day 1 (prior to randomization, or if within 3 months of
screening if patient is off antimuscarinic/anticholinergic drugs at the time of
urodynamic testing). Eligibility – Exclusion #2, page 18
Was: Volunteer has had previous or current botulinum toxin therapy of any serotype for any
urological condition or, treatment within 6 months of Randomization/Day 1 for
any other condition or use Now: Volunteer has had previous or current
botulinum toxin therapy of any serotype for any urological condition within 9
months or, treatment within 3 months of Randomization/Day 1 for any other
condition or use. 2. Bladder ultrasound no longer required: 10.1, page 19;
10.3.4, page 23; and 10.3.6, page 24
Now: Kidney ultrasound or results of exam conducted within 6 months of Visit 1. The HPR and ICD have been revised to reflect these changes.

**Amendment Submit Date:** 01/31/2013  
**Reason:** Other Amendment  
**Description:** This protocol is being funded by the DOD. For research determined to be
greater than minimal risk, DODI 3216.02 requires that the IRB approve, by
name, an independent research monitor with expertise consonant with the
nature of risk(s) identified within the research protocol. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Donald P. Griffith, MD, Chief of the Urology Service at MEDVAMC, is the research monitor for this study. As part of his function as Chief, he has participated in many clinical research studies and is aware of the concerns for the protection of human research subjects. He has knowledge of the mechanisms of the two study agents (onabotulinumtoxinA and oxybutynin). His research monitor functions may include: • observing recruitment and enrollment procedures and the consent process, • discussing with the investigators with regards to the protocol's study interventions and interactions, • reviewing monitoring plans and UPIRTSO reports; • reviewing data matching, data collection, and analysis In addition, Dr. Griffith shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. He shall also have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO. Dr. Griffith's CV and CITI MEDVAMC human subject's protection training documentation is attached in Section S.

Amendment Submit Date: 01/31/2013
Reason: Other Amendment
Description: This protocol is being funded by the DOD. For research determined to be greater than minimal risk, DODI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Donald P. Griffith, MD, Chief of the Urology Service at MEDVAMC, is the research monitor for this study. As part of his function as Chief, he has participated in many clinical research studies and is aware of the concerns for the protection of human research subjects. He has knowledge of the mechanisms of the two study agents (onabotulinumtoxinA and oxybutynin). His research monitor functions may include: • observing recruitment and enrollment procedures and the consent process, • discussing with the investigators with regards to the protocol's study interventions and interactions, • reviewing monitoring plans and UPIRTSO reports; • reviewing data matching, data collection, and analysis In addition, Dr. Griffith shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. He shall also have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO. Dr. Griffith's CV and CITI MEDVAMC human subject's protection training documentation is attached in Section S.

Amendment Submit Date: 06/19/2012
Reason: Other Amendment
Description: The VA Biomedical Laboratory Research and Development Service has requested the following changes: In the consent form: - Please indicate if the specimens will be shared with other researchers for other approved research protocols. - Please disclose any potential commercial benefits and if the subject will receive additional money or other benefits from future testing on their specimens. - Please indicate that no genetic testing will be performed

on specimens. - Clarify coding system. Changes to the HPR: - Clarify coding system of specimens sent to Dr. Chancellor. All requested changes have been completed.
April 10, 2014

CHRISTOPHER PATRICK SMITH
BAYLOR COLLEGE OF MEDICINE
UROLOGY

H-26296 - A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER 11-09-10-04)

APPROVAL VALID FROM 4/10/2014 TO 3/11/2015

Dear Dr. SMITH

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol and consent form(s) named above were approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants’ safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

RAYAN KAMAL AL JURDI, M.D., B.S.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
The consent form describes a double-blind, randomized study of OnabotulinumtoxinA (OnaBoNT-A) versus oral Oxybutynin in spinal cord injured patients with neurogenic detrusor overactivity (NDO). The study aims to assess the safety and efficacy of these treatments. The background explains NDO as a condition where the bladder is hyperactive, often resulting in urinary incontinence. Current treatments, such as drugs, have side effects. OnaBoNT-A has shown improvements in urinary leakage and bladder capacity in clinical trials. Oxybutynin ER relaxes bladder smooth muscle and has been shown to increase bladder capacity and reduce frequency of urine loss in patients with UI. The study is supported by the Department of Defense. The purpose is to determine if OnaBoNT-A is safe and effective when injected into the bladder for UI treatment, and whether it works better than Oxybutynin ER taken orally. The study also involves research on urine samples for bladder diseases and biomarkers.
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make-up of the urine cells) will be examined to learn if there are yet undiscovered reasons for urinary diseases.

OPTIONAL RESEARCH: Future research projects using your urine samples may lead to better treatment of urinary diseases.

Procedures
The research will be conducted at the following location(s): Baylor College of Medicine, Michael E. DeBakey Veterans Affairs Medical Center.

If you decide to be in this study, you will be asked to sign this informed consent document. You will be taking part in the study for at least 6-7 months and will visit the clinic at least 5 times.

This is a double blind study, which means that neither you nor your study doctor will know which study drugs you are receiving. However, your study doctor can get this information quickly in case of a health-related emergency.

You will be randomized to one of two treatments. The treatment you will be receiving is determined by random like the toss of a coin. You will have a 50-50 chance of receiving either treatment. The treatments are ARM 1: onaBoNT bladder injection and a placebo (sugar pill) oral medication once a day; or ARM 2: placebo (saline or salt water) bladder injection and Oxybutynin ER (like Ditropan) capsule once a day.

VISIT 1 - Screening
After your informed consent is obtained, the following will occur at least 2 weeks but not more than 4 weeks prior to Visit 2: randomization and bladder injection:

1. You will have a physical examination. The study staff will ask about your medical history including the medications you are now taking and procedures you have had.
2. Your vital signs (blood pressure, temperature and pulse rate) and weight will be measured.
3. You will have a kidney ultrasound or results of exam conducted within 6 months of Visit 1. An ultrasound test is a radiology technique, which uses high -frequency sound waves to produce images of the organs and structures of the body. The sound waves are sent through body tissues with a device called a transducer. The transducer is placed directly on top of the skin, which has a gel applied to the surface. The sound waves that are sent by the transducer through the body are then reflected by internal structures as "echoes." These echoes return to the transducer and are transmitted electrically onto a viewing monitor. After the ultrasound, the gel is easily wiped off.
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4. You will give about 3 teaspoons of blood to test the following:
   - To see if your blood count is normal.
   - If you are a female, to confirm that you are not pregnant.
   - If you are a male, to test your PSA (Prostate specific antigen) which is a test used to screen for cancer of the prostate.

5. You will give a urine sample for routine tests and to use as a baseline for research testing.

6. You will have urodynamic studies to give a baseline reading of what your bladder function is before you start the treatment. If you have had these studies within the past six months and you were not taking an medications for your overactive bladder, you will not need the studies at this visit. This test gives the doctors detailed information about the way your bladder and bladder outlet (the urethra) work when you try to urinate. It helps explain why you may have difficulty holding urine or urinary frequency. During this procedure, catheters with pressure sensors are placed through the urethra into your bladder and also into your rectum. The pressure in your bladder and rectum are measured while your bladder is filled with saline or dye solution. You will be asked questions about how full you feel and when you have the urge to urinate. You will be asked to urinate, if possible, during the study. X-rays and photos may be taken during the study.

7. If you are able to urinate, you will have a PVR (Post-Void Residual) test. The volume of fluid remaining in the bladder immediately after you urinate will be measured by catheterization (tube inserted into your bladder), or abdominal or vaginal ultrasound.

8. You will be given a bladder diary to keep track of the number of times you urinate, the amount, any leakage, etc. for 7 straight days in the week prior to next clinic visit.

9. You will be given a prescription for an antibiotic. You will take the antibiotic 3 days BEFORE your next visit, on the morning of the visit, and for 3 days AFTER the bladder injection.

VISIT 2: Randomization and Treatment (14 days to 6 weeks after Visit 1)

The following procedures and events will happen during this visit.

1. Your vital signs and weight will be measured.
2. If you are a female, you give about 2 teaspoons of blood to confirm that you are not pregnant.
3. You will give a urine sample for routine tests and to use as a baseline for research testing.
4. If you are able to urinate, you will have a PVR.
5. The study doctor or a study staff member will review your current medications and ask about any problems you may have had since the last study visit.
6. You will complete the Incontinence Quality of Life questionnaire (I-QOL) and Incontinence Quality of Life neurogenic module (I-QOLNM) questionnaires prior to treatment. It will take about 15-20 minutes to complete the questionnaires.
7. Your bladder diary will be reviewed by the study staff. You will be given a bladder diary to keep
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track of the number of times you urinate, the amount, any leakage, etc. for 7 straight days in the week prior to next clinic visit.

You will be randomized into your treatment group.

After randomization, the following events will occur:

8. Your bladder injection procedure will be done according to standard procedures in the clinic. The doctor will decide if you will be given a local anesthesia to lessen the pain before beginning the injection procedure. Your bladder will be filled with saline so that the area is free of urine. The injection will be given. The study doctor will discuss the procedure with you. After the injection, you will be observed for at least 30 minutes before you can go home. You will be instructed to continue your antibiotics for 3 more days.

9. You will be given the study oral medication dose while at the clinic and some to take home. You are to take the study medication once a day every day. You will be given a diary that you will complete to help you remember to take your medication. Please bring the pill bottle and the diary with you to your next clinic visit.

10. You will complete the bladder diary for 7 consecutive days in a row prior to next clinic visit in about 2 weeks.

VISIT 3: Telephone Visit (Day 3 to 5 after injection)

You will be contacted by telephone to discuss your well-being, any changes in your medications, your antibiotic compliance, and any side-effects or adverse events you may have experienced.

VISITS 4: Week 4 after injection (plus or minus 3 days)

1. Your vital signs and weight will be measured.
2. If you are able to urinate, you will have a PVR test.
3. If you are a female, you give about 2 teaspoons of blood to confirm that you are not pregnant.
4. You will give a urine sample for routine tests and research testing.
5. Your bladder diary will be reviewed by the study staff. You will be given a bladder diary to keep track of the number of times you urinate, the amount, any leakage, etc. for 7 straight days in the week prior to next clinic visit.
6. The study doctor or a study staff member will review your medications and ask about any adverse events you may have had.
7. You will complete the I-QOL, I-QOLNM, OAB-Patient Satisfaction with Treatment Questionnaire (OAB_PSTQ), and Patient Global Assessment (PGA) questionnaires. It will take you about 20 to 30
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minutes to complete them.
8. You will be given the study oral medication dose and the pill diary. Please bring the pill bottle and the diary with you to your next clinic visit.

VISIT 5: Week 12 after injection (plus or minus 3 days)

The procedures for this clinic visit are the same as VISIT 4. In addition, you will also undergo a urodynamic study.

VISIT 6: Week 24: End of Study/Study Exit (2 weeks plus or minus 3 days after injection)

1. You will undergo a physical examination that includes your vital signs and weight measurements.
2. If you are able to urinate, you will have a PVR test.
3. You will give a urine sample for routine tests and research testing.
4. You will give about 3 teaspoons of blood to check your general health.
5. If you are a female, you give about 2 teaspoons of blood to confirm that you are not pregnant.
6. You will have a kidney ultrasound.
7. You will give your completed bladder diary to the study doctor or staff.
8. The study doctor or a study staff member will review your medications and ask about any adverse events you may have had.
9. You will complete same 4 questionnaires as you did in VISIT 4.

This ends your participation in this research study.

If you are a male, you will have a total of approximately 6 teaspoons of blood drawn during the study. If you are a female, you will have a total of approximately 12 teaspoons of blood drawn during the study.

A portion of your urine samples will be sent to the Beaumont Research Institute at the Oakland University William Beaumont School of Medicine in Royal Oak, MI for research testing conducted under the supervision of Dr. Michael B. Chancellor. The samples will be coded so that only your study doctor will know how to link your name and other identifying information with the coded sample. The staff at the testing site will not be able to link the code to your information.

OPTIONAL RESEARCH:

With your permission, after research testing required for this study is completed, the remaining portion of your samples will be stripped of the code and will be banked for future use. It will be kept until it is
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all gone. Your samples will not be sold or transferred to anyone else but may be shared with the study doctor's colleagues for approved research studies. If at any time you withdraw from this study, you will not be able to get your urine samples back. You can't request that they be destroyed because the samples can't be linked to you.

Genetic testing will not be conducted on your specimens.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

You can participate in this study if you choose not to have your samples banked.

Please see next to last page of this consent form to choose your choice for this optional research.

Your research doctor may never be able to provide you with your research related health information.

Potential Risks and Discomforts

OnaBoNT-A: It is expected that you may have some or all of the following side effects when given onaBoNT-A. Other side effects may occur which were not seen before. Side effects are usually temporary and manageable. However, it is possible they could cause serious disease or death. The study may include risks that are unknown at this time.

There have been rare reports of serious and/or immediate or even deadly abnormally sensitive reactions after treatment with onaBoNT-A. These reactions include allergic reaction, skin rash, itching, swelling, and difficulty in breathing.

It is a rare possibility that the injection of onaBoNT-A could lead to botulism. The classic symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. The doctor's examination may reveal that the gag reflex and the deep tendon reflexes like the knee jerk are decreased or absent.

There have been rare reports of sudden death, sometimes associated with difficulty in swallowing or pneumonia. There have also been rare reports of heart problems (including irregular heart beats and heart attack, some resulting in death). Some of these patients already had or were at risk for heart disease. It is not known if onaBoNT-A actually caused these problems.

It should not be used when infection is present at the injection site or if you are known to be abnormally sensitive to onaBoNT-A.
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The following events have been observed since onaBoNT-A has been marketed: skin rash, itching, and allergic reaction. In general, these side effects occur within the first week following injection and, while usually temporary, they may last several months. Pain, tenderness, or bruising around the injection site may also occur. Local weakness of the injected muscle(s) is expected. Weakness of nearby muscles may also occur due to spread of onaBoNT-A.

OnaBoNT-A contains albumin, which comes from human blood. Although the blood is rigorously tested, there is an extremely remote risk for the transmission of viruses and similar infectious agents.

OXYBUTYNIN ER: Common Side Effects: Blurred vision; constipation; diarrhea; dizziness; drowsiness; dry eyes, nose, skin, or mouth; headache; indigestion; nausea; runny nose; stomach pain or upset; trouble sleeping; weakness

Severe Side Effects: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); confusion; difficult or painful urination; fast or irregular heartbeat; fever; hallucinations; mental or mood changes (e.g., agitation); seizures; swelling of the hands, ankles, or feet; vision problems.

Oxybutynin ER is contraindicated in patients with urinary retention, gastric retention and other severe decreased gastrointestinal motility conditions, uncontrolled narrow-angle glaucoma and in patients who are at risk for these conditions.

Oxybutynin ER is also contraindicated in patients who have demonstrated hypersensitivity to the drug substance or other components of the product.

The concomitant use of Oxybutynin ER with other anticholinergic drugs (used to relieve cramps or spasms of the stomach, intestines, and bladder) or with other agents that produce dry mouth, constipation, somnolence (drowsiness), and/or other anticholinergic-like effects may increase the frequency and/or severity of such effects.

The safety of Oxybutynin ER administered to women who are or who may become pregnant or are breastfeeding has not been established. Therefore, Oxybutynin chloride should not be given to pregnant women unless, in the judgment of the physician, the probable clinical benefits outweigh the possible hazards.

LIDOCAINE® (given to deaden the area around the injection site): The amount of Lidocaine that you will receive usually does not cause any side effects.
Often, the following side effects may be experienced:

- lightheadedness
- nervousness
- anxious or scared
- feeling of well being and great happiness
- confusion
- dizziness
- drowsiness
- ringing or buzzing in the ear
- blurred or double vision
- vomiting
- sensations of heat, cold or numbness
- slight jerking motions
- shaking
- convulsions or seizures
- loss of awareness of surroundings
- difficulty breathing or not breathing at all
- slow heart beat
- low blood pressure
- stopping of the heart

Extremely rare side effects include hives, swelling, and shock.

PLACEBO: Since placebo has no active drug, your overactive bladder condition may become worse, stay the same or improve.

ANTIBIOTICS: An antibiotic may cause upset stomach, diarrhea, vomiting, skin rash, itching, hives, difficulty breathing or swallowing, wheezing, unusual bleeding or bruising, sore throat, painful mouth or throat sores, and vaginal infection. Please read the package insert that will be provided for additional information.

CYSTOSCOPY WITH BLADDER INJECTION: The discomfort is nearly identical to being catheterized, which generally causes slight to moderate discomfort. There will be a feeling of fullness in the bladder and a sensation to empty during the cystoscopy examination. Bleeding, infection, damage to urethra or surrounding structures may occur.
PVR: The risks of having a catheter placed in the bladder for draining the residual urine are infection of the urinary tract, injury to the urethra caused by rough insertion of the catheter, narrowing of the urethra due to scar tissue caused by the insertion of a catheter, injury to the bladder caused by incorrect insertion of the catheter.

URODYNAMICS: Generally the risks of an urodynamic study are low and are no more than those of a Foley Catheter insertion, which include the possibility of infection, trauma to the urethra or prostate, traumatic bleeding from the catheterization, discovery of previously unsuspected urethral stricture with inability to get the urodynamics catheter into the bladder.

Patients with a spinal cord injury generally occurring at the Thoracic 5 (T-5) level and above have a risk of experiencing autonomic dysreflexia during bladder filling during the urodynamic or study treatment procedures. Autonomic dysreflexia can develop suddenly, and is a possible emergency situation. Symptoms of autonomic dysreflexia include the following: elevation in blood pressure, headache, goose pimples, sweating above the level of injury, nasal congestion, slow pulse, blotching of the skin, and restlessness. If not treated promptly and correctly, it may lead to seizures, stroke, and in some cases, even death. To minimize this risk continuous blood pressure monitoring is performed throughout the study.

ULTRASOUND: Ultrasound testing is painless and harmless but the volunteer might experience anxiety in anticipation of the test. Ultrasound tests involve no radiation and studies have not revealed any adverse effects.

BLOOD DRAWS: Inserting needles into veins for collecting blood may be uncomfortable. Risks include slight bruising at the puncture site, fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, bleeding from the site, and the remote possibility of infection at the site of the needle puncture. Fainting is usually harmless, of short duration, and typically produces feelings of weakness, sweating, slowing of the heart rate and an abnormal decrease in blood pressure. Care will be taken to avoid these complications.

QUESTIONNAIRES: Completing the questionnaires may cause you to have or to experience some level of emotional discomfort due to the personal nature of the questions. The study doctor and staff will maintain a professional and caring attitude while administering the questionnaires.

LOSS OF CONFIDENTIALITY: The loss regarding research information is a possibility, although, the risk is extremely small. The investigator and his staff will make every effort to maintain the confidentiality. Your urine specimens will labeled with your subject code before being sent to Dr. Chancellor's laboratory. The laboratory personnel will not be able to know that these specimens are
Subject Name: ________________________________ Date: ________________

Subject Initials: ________________________________

Principal Investigator: CHRISTOPHER PATRICK SMITH

VAMC: 

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Your Study documents kept at Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) may include your initials and subject code but no other identifying information. Any of your information or specimens will not contain your initials if they leave MEDVAMC.

PREGNANCY: It is possible that the medicines used in this study could injure a fetus if volunteer or volunteer's partner becomes pregnant while taking them. Pregnant and/or lactating women will be excluded from the study. Because of the potential risks involved, pregnancy should not occur during participation in this study. The following methods of contraception, if properly used, are generally considered reliable for females of childbearing potential who may participate in the study: oral contraceptives, patch contraceptives, injection contraceptives, male condom with intravaginal spermicide, diaphragm or cervical cap with spermicide, vaginal contraceptive ring, intrauterine device, surgical sterilization (bilateral tubal ligation), vasectomized partner(s), or total sexual abstinence. Both males and females should use birth control.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

Potential Benefits
The benefits of participating in this study may be: improvement in urinary incontinence symptoms, decrease in the occurrence of urinary tract infections, decrease in the number of required catheterizations, and an ease of the financial burden of buying protective garments. However, you may receive no benefit from participating.

Alternatives
The following alternative procedures or treatments are available if you choose not to participate in this study: oral medications or invasive surgery to enlarge your bladder with intestine.

Subject Costs and Payments
Standard of Care: Services provided at the MEDVAMC for this disease state include clinic visits, PVRs, Kidney ultrasounds (Visits 1 and End of Study), urodynamics studies, PSA, and urinalyses. These services will be billed/paid as normally done through the MEDVAMC.

Research Costs: The events and procedures that will be paid by the study sponsor are the kidney ultrasound at Visit 2, the pregnancy tests at Visits 1, 2, 4, 5, and 6 and all study medications.
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You will receive $50 for completing each of the study visits 2, 4, 5, and 6 for a total of $200 if all visits are completed. In order for you to receive the stipend, you will provide your name, address, telephone number, and Social Security number. You will complete the BCM Research Participant/Donor Compensation form. A check will be mailed to you.

Research Related Injury

If you experience a research related injury, please contact the Dr. Smith immediately at 713-798-4001. He will instruct you on what procedures to follow in order to receive treatment for the injury.

Women of Childbearing Potential

It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. Because of the potential risks involved, you or your partner should not become pregnant while you are participating in this study.

If you are sexually active or become sexually active and can get pregnant or can get your partner pregnant, you must agree to use one of the following forms of birth control every time you have sex:

* oral contraceptives ("the pill"),
* intrauterine devices (IUDs),
* contraceptive implants under the skin, or contraceptive injections,
* condoms with foam.

Should you become pregnant while on this study, you must immediately notify the study personnel.

The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can choose not to provide this information.

Subject’s Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time.
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Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Your Health Information

Your signature on this form means that you give permission for the use and disclosure of your protected health information for this research study. Federal law requires that the Michael E. Debakey Veterans Affairs Medical Center protect health information linked to your identity. The procedures section above provides the specific information and the person(s) who would use or disclose it.

If you decide not to give your permission for the use and disclosure of your protected health information as we have described for this study, you will receive access to the same treatment, payment, enrollment or eligibility for benefits as you normally would.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

If you decide to take part in the study, your protected health information will not be given out except as allowed by the regulations or as described in this form. The results of the data from the study may be published. However, you will not be identified by name. People who receive your protected health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

You may decide that you no longer allow protected health information that identifies you to be used or disclosed for this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor this decision unless the researchers have already acted in reliance on your information. Then it will not be possible to honor your decision in this way.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.
The investigator, CHRISTOPHER PATRICK SMITH, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: CHRISTOPHER PATRICK SMITH at 713-798-4001 24 hours a day.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Under Federal Regulations, the VA Medical facility shall provide necessary medical treatment to you as a research subject injured as a result by participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Michael E. DeBakey VA Medical Center. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You do not waive any liability rights for personal injury by signing this form.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC. If you would like to verify the validity of the study and authorized contacts, you may speak with the Michael E. DeBakey Veterans Affairs Medical Center Research Office at 713-794-7918 or 713-794-7566.

SAMPLE STORAGE: You are being asked to agree to allow samples of your urine samples which will be stored as described in the Procedures section of this informed consent document, to be used for current research use. You are also being asked to agree to allow the use of stored materials for future research use. Complete confidentiality will be maintained and these samples will not be tracked back to you, except by using records available only to the Principal Investigators, the Co-Investigators, and your urologist.

PLEASE CIRCLE YOUR CHOICES AND INITIAL:

Samples used for current research:  ____YES              ____NO              _______________INITIALS
Subject Name: _______________________________ Date: __________

Subject Initials: ____________________________________________

Principal Investigator: CHRISTOPHER PATRICK SMITH

VAMC: __________

H-26296 - A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF
ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD
INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER
11-09-10-04)

Samples used for future research: ____YES ____NO _______________INITIALS
Subject Name: ___________________________ Date: __________
Subject Initials: ___________________________

Principal Investigator: CHRISTOPHER PATRICK SMITH VAMC: __________

H-26296 - A DOUBLE-BLIND, RANDOMIZED STUDY OF THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA (ONABONT-A) VERSUS ORAL OXYBUTYNIN IN SPINAL CORD INJURED PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY (PROTOCOL NUMBER 11-09-10-04)

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_________________________________________ Date
Subject

_________________________________________ Date
Investigator or Designee Obtaining Consent

_________________________________________ Date
Witness
Incontinence Quality of Life Instrument Neurogenic Module

PLEASE READ THIS CAREFULLY

PLEASE CHOOSE THE RESPONSE THAT APPLIES BEST TO YOU RIGHT NOW AND CIRCLE THE NUMBER OF YOUR ANSWER.

IF YOU ARE UNSURE ABOUT HOW TO ANSWER A QUESTION, PLEASE GIVE THE BEST ANSWER YOU CAN.

THERE ARE NO RIGHT OR WRONG ANSWERS.

YOUR ANSWERS WILL BE KEPT STRICTLY
Incontinence Quality Of Life Neurogenic Module

(Please circle the number of your answer.)

1. I have to limit caffeine drinks or alcohol because of my urinary problems or incontinence.
   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

2. I worry about the long-term effect of catheterizations on my urinary tract infections or other health problems.
   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

3. Accessibility and privacy in public toilets are important to me.
   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

Continued on next page
(Please circle the number of your answer.)

4. It bothers me to have to catheterize on a regular schedule.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

5. It bothers me to have to use incontinence pads or diapers.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

END OF QUESTIONNAIRE

THANK YOU FOR YOUR RESPONSES
INCONTINENCE QUALITY OF LIFE INSTRUMENT (I-QOL)

PLEASE READ THIS CAREFULLY

ON THE FOLLOWING PAGES YOU WILL FIND SOME STATEMENTS THAT HAVE BEEN MADE BY PEOPLE WHO HAVE URINARY INCONTINENCE (LEAKING URINE WHEN YOU DON'T WANT TO).

PLEASE CHOOSE THE RESPONSE THAT APPLIES BEST TO YOU RIGHT NOW AND CIRCLE THE NUMBER OF YOUR ANSWER.

IF YOU ARE UNSURE ABOUT HOW TO ANSWER A QUESTION, PLEASE GIVE THE BEST ANSWER YOU CAN.

THERE ARE NO RIGHT OR WRONG ANSWERS.

YOUR ANSWERS WILL BE KEPT STRICTLY
Incontinence Quality Of Life

Your Feelings

(Please circle the number of your answer.)

1. I worry about not being able to get to the toilet on time.
   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

2. I worry about coughing or sneezing because of my urinary problems or incontinence.
   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

3. I have to be careful standing up after I’ve been sitting down because of my urinary problems or incontinence.
   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

Continued on next page
(Please circle the number of your answer.)

4. I worry about where toilets are in new places.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

5. I feel depressed because of my urinary problems or incontinence.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

6. Because of my urinary problems or incontinence, I don't feel free to leave my home for long periods of time.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

Continued on next page
7. I feel frustrated because my urinary problems or incontinence prevents me from doing what I want.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

8. I worry about others smelling urine on me.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

9. My urinary problems or incontinence is always on my mind.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

Continued on next page
10. It's important for me to make frequent trips to the toilet.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

11. Because of my urinary problems or incontinence, it's important to plan every detail in advance.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

12. I worry about my urinary problems or incontinence getting worse as I grow older.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

Continued on next page
13. I have a hard time getting a good night of sleep because of my urinary problems or incontinence.

1. EXTREMELY  
2. QUITE A BIT  
3. MODERATELY  
4. A LITTLE  
5. NOT AT ALL

14. I worry about being embarrassed or humiliated because of my urinary problems or incontinence.

1. EXTREMELY  
2. QUITE A BIT  
3. MODERATELY  
4. A LITTLE  
5. NOT AT ALL

15. My urinary problems or incontinence makes me feel like I'm not a healthy person.

1. EXTREMELY  
2. QUITE A BIT  
3. MODERATELY  
4. A LITTLE  
5. NOT AT ALL

Continued on next page
16. My urinary problems or incontinence makes me feel helpless.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

17. I get less enjoyment out of life because of my urinary problems or incontinence.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

18. I worry about wetting myself.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

Continued on next page
19. I feel like I have no control over my bladder.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

20. I have to watch what or how much I drink because of my urinary problems or incontinence.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

21. My urinary problems or incontinence limit my choice of clothing.

   1. EXTREMELY
   2. QUITE A BIT
   3. MODERATELY
   4. A LITTLE
   5. NOT AT ALL

Continued on next page
(Please circle the number of your answer.)

22. I worry about having sex because of my urinary problems or incontinence.

1. EXTREMELY
2. QUITE A BIT
3. MODERATELY
4. A LITTLE
5. NOT AT ALL

END OF QUESTIONNAIRE

THANK YOU FOR YOUR RESPONSES
OAB-PATIENT SATISFACTION WITH TREATMENT QUESTIONNAIRE (OAB_PSTQ)

Please answer each question by checking the box which best describes your situation.

Answers should come from your alone, not family, friends, or the doctor's staff.

1. In the past 4 weeks, how satisfied have you been overall with your current or recent treatment(s)

☐ Very Satisfied
☐ Somewhat Satisfied
☐ Neutral
☐ Somewhat Dissatisfied
☐ Very Dissatisfied
☐ Does not apply to me

2. In the past 4 weeks, how satisfied have you been during your treatment's effect on how frequently you have to urinate during the day?

☐ Very Satisfied
☐ Somewhat Satisfied
☐ Neutral
☐ Somewhat Dissatisfied
☐ Very Dissatisfied
☐ Does not apply to me

Continued on next page
(Please place a check (✓) by your answer.)

3. In the past 4 weeks, how satisfied have you been during your treatment's effect on how frequently you have to urinate during the night?
   - Very Satisfied
   - Somewhat Satisfied
   - Neutral
   - Somewhat Dissatisfied
   - Very Dissatisfied
   - Does not apply to me

4. In the past 4 weeks, how satisfied have you been during your treatment's effect on how frequently you have 'wetting accidents' due to laughing, coughing, sneezing, or physical exercise?
   - Very Satisfied
   - Somewhat Satisfied
   - Neutral
   - Somewhat Dissatisfied
   - Very Dissatisfied
   - Does not apply to me

5. In the past 4 weeks, how satisfied have you been during your treatment's effect on the uncontrollable urge to urinate?
   - Very Satisfied
   - Somewhat Satisfied
   - Neutral
   - Somewhat Dissatisfied
   - Very Dissatisfied
   - Does not apply to me

Continued on next page

Smith H-26296          Subject ID#_________    Visit # __________
(Please place a check (✓) by your answer.)

6. In the past 4 weeks, how satisfied have you been during your treatment's effect on your ability to freely engage in social, work, or leisure activities with confidence (e.g., sports, hobbies, shopping, etc.)?

☐ Very Satisfied
☐ Somewhat Satisfied
☐ Neutral
☐ Somewhat Dissatisfied
☐ Very Dissatisfied
☐ Does not apply to me

7. In the past 4 weeks, how satisfied have you been during your treatment's effect on your enjoyment of life?

☐ Very Satisfied
☐ Somewhat Satisfied
☐ Neutral
☐ Somewhat Dissatisfied
☐ Very Dissatisfied
☐ Does not apply to me

8. In the past 4 weeks, how satisfied have you been during your treatment's effect on reducing fatigue and sleep interruptions?

☐ Very Satisfied
☐ Somewhat Satisfied
☐ Neutral
☐ Somewhat Dissatisfied
☐ Very Dissatisfied
☐ Does not apply to me

Continued on next page
(Please place a check (✓) by your answer.)

9. In the past 4 weeks, how satisfied have you been during your treatment's effect on your travel?
   - Very Satisfied
   - Somewhat Satisfied
   - Neutral
   - Somewhat Dissatisfied
   - Very Dissatisfied
   - Does not apply to me

10. In the past 4 weeks, how satisfied have you been during your treatment's effect on your relationships with loved ones?
    - Very Satisfied
    - Somewhat Satisfied
    - Neutral
    - Somewhat Dissatisfied
    - Very Dissatisfied
    - Does not apply to me

11. In the past 4 weeks, how satisfied have you been during your treatment's effect on your ability to engage in sexual activity?
    - Very Satisfied
    - Somewhat Satisfied
    - Neutral
    - Somewhat Dissatisfied
    - Very Dissatisfied
    - Does not apply to me

Continued on next page
12. In the past 4 weeks, how satisfied have you been with the amount of money you spent on treatment(s) for overactive bladder or urinary incontinence?

- [ ] Very Satisfied
- [ ] Somewhat Satisfied
- [ ] Neutral
- [ ] Somewhat Dissatisfied
- [ ] Very Dissatisfied
- [ ] Does not apply to me

13. In the past 4 weeks, how satisfied have you been during your treatment's ability to reduce your embarrassment due to your overactive bladder or urinary incontinence?

- [ ] Very Satisfied
- [ ] Somewhat Satisfied
- [ ] Neutral
- [ ] Somewhat Dissatisfied
- [ ] Very Dissatisfied
- [ ] Does not apply to me

14. In the past 4 weeks, how would you rate the side effects due to your treatment(s)?

- [ ] No Side Effects
- [ ] Mild Side Effects
- [ ] Moderate Side Effects
- [ ] Severe Side Effects

Continued on next page
Questions 15 and 16 should only be answered at the **DAY 1** visit PRIOR to the administration of the study medication.

15. Please list your top 1 or 2 primary goal(s) (top 1 or 2 only) for treatment of your overactive bladder.

1. __________________________________________________________________________

2. __________________________________________________________________________

16. What are your top 1 or 2 primary expectation(s) (top 1 or 2 only) for treatment of your overactive bladder?

1. __________________________________________________________________________

2. __________________________________________________________________________

Questions 15 and 16 should only be answered at follow-up visits AFTER the study drug administration.

15. Looking back at our primary goal(s) for treatment, how would you rate how effectively the treatment helped you achieve your stated goals?

Goal 1:

☐ No Progress in Achieving this Goal
☐ Some Progress in Achieving this Goal
☐ Moderate Progress in Achieving this Goal
☐ Significant Progress in Achieving this Goal
☐ Complete Achievement of this Goal.

Continued on next page
Goal 2 (if listed at baseline):

☐ No Progress in Achieving this Goal
☐ Some Progress in Achieving this Goal
☐ Moderate Progress in Achieving this Goal
☐ Significant Progress in Achieving this Goal
☐ Complete Achievement of this Goal.

16. Looking back at our primary expectation(s) for treatment, how would you rate how effectively the treatment met your stated expectations?

Goal 1:

☐ Did not meet this Expectation
☐ Somewhat met this Expectation
☐ Moderately met this Expectation
☐ Significantly met this Expectation
☐ Exceeded this Expectation

Goal 2 (if listed at baseline):

☐ Did not meet this Expectation
☐ Somewhat met this Expectation
☐ Moderately met this Expectation
☐ Significantly met this Expectation
☐ Exceeded this Expectation

Thank you. You have completed this questionnaire
PATIENT GLOBAL ASSESSMENT (PGA)

1. Since your last clinic visit, has there been any change in your overall symptoms related to your overactive bladder problems?

Place "X" next to the statement that most accurately reflects your opinion:

________ -7  A very great deal worse
________ -6  A great deal worse
________ -5  A good deal worse
________ -4  Moderately worse
________ -3  Somewhat worse
________ -2  A little worse
________ -1  Almost the same, hardly any worse at all
________  0   No change
________  1   Almost the same, hardly any better at all
________  2   A little better
________  3   Somewhat better
________  4   Moderately better
________  5   A good deal better
________  6   A great deal better
________  7   A very great deal better

Continued on next page
1. Since your last clinic visit, has there been any change in your overall quality of life related to your overactive bladder problems?

**Place "X" next to the statement that most accurately reflects your opinion:**

<table>
<thead>
<tr>
<th>Score</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>-7</td>
<td>A very great deal worse</td>
</tr>
<tr>
<td>-6</td>
<td>A great deal worse</td>
</tr>
<tr>
<td>-5</td>
<td>A good deal worse</td>
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<tr>
<td>-4</td>
<td>Moderately worse</td>
</tr>
<tr>
<td>-3</td>
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</tr>
<tr>
<td>-2</td>
<td>A little worse</td>
</tr>
<tr>
<td>-1</td>
<td>Almost the same, hardly any worse at all</td>
</tr>
<tr>
<td>0</td>
<td>No change</td>
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<tr>
<td>1</td>
<td>Almost the same, hardly any better at all</td>
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<td>2</td>
<td>A little better</td>
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<td>3</td>
<td>Somewhat better</td>
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<td>Moderately better</td>
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<td>5</td>
<td>A good deal better</td>
</tr>
<tr>
<td>6</td>
<td>A great deal better</td>
</tr>
<tr>
<td>7</td>
<td>A very great deal better</td>
</tr>
</tbody>
</table>

*Continued on next page*
3. Since your last clinic visit, has there been any change in your activity limitations related to your overactive bladder problems?

Place "X" next to the statement that most accurately reflects your opinion:

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>-7</td>
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<tr>
<td>-6</td>
<td>A great deal worse</td>
</tr>
<tr>
<td>-5</td>
<td>A good deal worse</td>
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<td>-4</td>
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<tr>
<td>-3</td>
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</tr>
<tr>
<td>-2</td>
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<tr>
<td>-1</td>
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<td>6</td>
<td>A great deal better</td>
</tr>
<tr>
<td>7</td>
<td>A very great deal better</td>
</tr>
</tbody>
</table>

Continued on next page
4. Since your last clinic visit, has there been any change in your overall emotions related to your overactive bladder problems?

Place "X" next to the statement that most accurately reflects your opinion:

_______  -7  A very great deal worse
_______  -6  A great deal worse
_______  -5  A good deal worse
_______  -4  Moderately worse
_______  -3  Somewhat worse
_______  -2  A little worse
_______  -1  Almost the same, hardly any worse at all
_______   0   No change
_______   1   Almost the same, hardly any better at all
_______   2   A little better
_______   3   Somewhat better
_______   4   Moderately better
_______   5   A good deal better
_______   6   A great deal better
_______   7   A very great deal better

Thank you. This completes the questionnaire.
STUDY DRUG DIARY

The study drug comes as a capsule to take by mouth. It is usually taken once a day at the same time every day.

Swallow the capsule whole with the aid of liquids; do NOT split, chew, crush, or open them.

The capsules should be stored at approximately 77 degrees but no lower than 59 degrees or higher than 86 degrees. Protect from moisture and humidity.

Do NOT stop taking oxybutynin without talking to your doctor or a research study team member.

Keep the capsules and all medicines out of reach of children.

You MUST bring the unused study drug with you at each visit.

You MUST complete the drug diary on the next page.

Take the study drug exactly as directed. Do not take more or less of it or take it more often than instructed by the doctor or a research study team member.
# STUDY DRUG DIARY

Subject Number _____________

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Example:

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RETURN DIARY, REMAINING CAPSULES, AND CAPSULE CONTAINER
Subject Number _____________

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<th>DATE</th>
<th>TIME PILL WAS TAKEN</th>
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RETURN DIARY, REMAINING CAPSULES, AND CAPSULE CONTAINER
Subject Number _____________

<table>
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RETURN DIARY, REMAINING CAPSULES, AND CAPSULE CONTAINER
onaBoNT-A vs. Oxybutynin for Spinal Cord Injuries with Overactive Bladders

7-DAY URINE DIARY

Volunteer ID# ____________  Visit # ___________

The diary is to be completed for the 7 days in a row the week before your clinic visit. Write the current date and diary day in the **DATE** row for each day.

At the time you experience an accidental leakage of urine, rate the episode as follows in the **Leakage** column:
- 1 = damp or a few drops of urine
- 2 = wet your underwear or pad
- 3 = soaked underwear/clothes or emptied bladder. You may have several accidents during an hour. Please record each event.

In the **Void** column, place a check mark (✓) each time you urinate in the toilet.

In the **CIC** column, please place a check each time you catheterize.

In the **Amount** column, indicate each time the number of ccs you urinated OR catheterized

<table>
<thead>
<tr>
<th>DATE</th>
<th>TIME</th>
<th>Leakage</th>
<th>Void</th>
<th>CIC</th>
<th>Amount</th>
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1 = Damp or a few drops of urine on underwear;

2 = Wet your underwear or pad;

3 = Soaked underwear/clothes or emptied bladder
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CURRICULUM VITAE

I. GENERAL BIOGRAPHICAL INFORMATION

A. Personal:

1. **Name:** Christopher Patrick Smith, M.D., M.B.A., M.S.S.
   **Address:**
   Academic/Research:
   Michael E. DeBakey Veterans Affairs Medical
   Houston, TX 77030
   Clinical:
   Baylor College of Medicine Medical Center
   7200 Cambridge Street, 10th Floor, Suite B Houston, TX 77030

B. Education:

1. **Undergraduate Education:**
   08/1986-05/1990 The George Washington University Washington, DC
   Bachelor of Science
   (Zoology)

2. **Medical Education or Graduate Education:**

   08/1990-06/1994 Northwestern University Medical School
   01/2001-09/2002 Chicago, IL Doctor of Medicine
   05/01/2011-07/27/2012 University of Pittsburgh
   Pittsburgh, PA
   Master of Business Administration
   U.S. Army War College
   Carlisle, PA
   Master of Strategic Studies
3. **Postgraduate Training:**

- **06/1994-07/1995** Intern and Resident in General Surgery
  Baylor College of Medicine
  Houston, TX

- **07/1995-01/1996** Resident in Urology
  Scott Department of Urology
  Baylor College of Medicine
  Houston, TX

- **07/2000-06/2002** NIH/K12 Physician Scientist Fellow in Neurourology and Female Urology
  Department of Urology
  University of Pittsburgh School of Medicine

C. **Academic Appointments:**

1. **Current Faculty Positions at BCM:**

   - **08/2013-Present** Chief, SCI Urology
     Michael E. DeBakey Veterans Affairs Medical Center

   - **05/2008-Present** Associate Professor of Urology
     Scott Department of Urology
     Baylor College of Medicine
     One Baylor Plaza
     Houston, TX 77030

   - **07/2002-04/2008** Assistant Professor of Urology
     Scott Department of Urology
     Baylor College of Medicine
     One Baylor Plaza
     Houston, TX 77030

2. **Previous Faculty Position(s) at Other Institutions:**

   - **07/2000-06/2002** Visiting Instructor
     Department of Urology
     University of Pittsburgh
     3471 Fifth Avenue #700
     Pittsburgh, PA 15213

3. **Current Courtesy Faculty Appointment(s) at Other Institutions:** Not Applicable

D. **Other Advanced Training Experience:**

1. **Formal Sabbatic Leave:** Not Applicable
2. **Other Specialized Training Following Academic Appointment:**

<table>
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<td>05/01/2008-12/15/2011</td>
<td>Career Development Award, Spinal Cord Electrophysiological Methods, Department of Veterans Affairs</td>
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E. **Other Information:**

1. **Honors or Awards:**

<table>
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<td>1993</td>
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<td>05/2000</td>
<td>American Foundation of Urological Disease Travel Award</td>
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<td>07/2000-06/2002</td>
<td>NIH/K12 Physician Scientist Fellowship in Neurourology and Female Urology</td>
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<td>07/2000-06/2002</td>
<td>American Foundation of Urological Disease Scholar</td>
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<td>02/2006</td>
<td>Paul Zimskind Award, Best Young Investigator, Society of Urodynamics and Female Urology</td>
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<tr>
<td>05/01/2008-12/15/2011</td>
<td>Career Development Award, Department of Veterans Affairs</td>
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<td>2008</td>
<td>Second Prize Winner, 2008 Annual Jack Lapides Essay Contest on Urodynamics and Neurourology Research</td>
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<td>05/01/2008-05/01/2011</td>
<td>Astellas/American Urological Association Foundation Rising Star in Urology Award</td>
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<td>06/2008</td>
<td>Apple Award, American Spinal Injury Association (ASIA)</td>
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<td>05/2008</td>
<td>Best Poster Award, American Urological Association Annual Meeting</td>
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<td>2010</td>
<td>Listed in Castle Connolly’s <em>America’s Top Doctors</em></td>
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<td>05/2011</td>
<td>Best Poster Award, American Urological Association Annual Meeting</td>
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<td>Listed in U.S. News Top Doctors List, developed by <em>U.S. News &amp; World Report</em> in collaboration with Castle Connolly Medical Ltd.</td>
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<td>2013</td>
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2. **Board Eligibility/Certification:**

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<td>02/28/2005-02/28/2025</td>
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3. Other Nonacademic Positions:

Military Experience:

a. Appointments:

- 1998-2001 Captain, United States Army Reserve Corps
- 2001-2007 Major, United States Army Reserve Corps
- 2007-2014 Lieutenant Colonel, United States Army Reserve Corps
- 2014-Present Colonel, United States Army Reserve Corps

b. U.S. Decorations/Badges:

- Army Commendation Medal
- Army Achievement Medal
- Army Reserve Components Achievement Medal
- National Defense Service Medal
- Armed Forces Reserve Medal with Bronze Hourglass and M-Device x 3
- Global War on Terrorism Expeditionary Medal
- Global War on Terrorism Service Medal
- Army Service Ribbon
- Army Overseas Training Ribbon
- Meritorious Unit Commendation Ribbon
- Army Superior Unit Award Ribbon

c. Service:

- Source and Date of Commission: Direct Commission, August 5, 1998
- Years of Active Commissioned Service: Over 1 year
- Total Years of Service: Over 16 years

d. Record of Duty Assignments:

- 1999-2002 Urologist, Morrow USAR Center, Morrow, GA
- 2002-2003 Urologist, SGM Marcario Garcia USAR Center, Houston, TX
- 2003 Urologist, Landstuhl Regional Medical Center, Landstuhl, Germany (MOB for OEF)
- 2003-2005 Urologist, SGM Marcario Garcia USAR Center, Houston, TX
- 2005 Deputy Director of Urology, Womack Army Medical Center, Fort Bragg, NC (MOB for OEF)
- 2005-2007 Urologist, SGM Marcario Garcia USAR Center, Houston, TX
2007-2009  Branch Immateriel Officer, HQ US Army SOCOM Support Unit, Tampa, FL

2008  Senior Surveillance and Medical Operations Officer, CENTCOM AOR (MOB for OEF)

2009-Present  Urologist, Individual Ready Reserve, St. Louis, MO

II. RESEARCH INFORMATION

A. Research Support:

Active:

Protocol #05-09-30-03, Smith (PI)  04/2011-04/2015
Title: H-25362: Effect of Botulinum Neurotoxin Type A Prostate Injections on Neurogenesis and Gene Profile Expression in Men With Localized Prostate Cancer and Lower Urinary Tract Symptoms/BPH. NCT01520441

Protocol # 02-10-10-05, Smith (PI)  04/01/2012-03/31/2016  0.60 calendar VA Merit
Title: A Double-Blind, Randomized Study of the Efficacy of Onabotulinumtoxin-A (Onabont-A) Versus Oral Tamsulosin in Men with BPH and LUTS

Protocol 11-09-10-04, Smith (PI)  09/30/2012-09/29/2016  1.2 calendar DOD
Title: A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO
The main purpose of this proposal that incorporates novel urine biomarker testing into existing clinical methodologies is to: 1) evaluate the efficacy of 200 U BoNT-A injected into the detrusor versus oral oxybutynin for the treatment of urinary incontinence (UI) caused by neurogenic detrusor overactivity (NDO) in spinal cord injured patients and 2) to determine the potential role of urine biomarkers in guiding the process of patient selection and identify surrogate predictors of treatment outcomes.

Previous:

DK069988, Smith (Co-I)  03/01/2005-02/28/2010  10% NIH/NIDDK
Title: Nicotinic-Purinergic Modulation of Bladder Contraction
Goals: To explore mechanisms underlying changes in nicotinic-purinergic interaction that occurs in bladders after spinal cord injury or after bladder outlet obstruction.

Allergan, Inc., Smith (PI)  11/01/2005-10/31/2008  2%
Title: Effect of a Novel Conjugate of BTX-A Light Chain in Rat Models of Bladder Hyperactivity

NIDRR Smith (PI)  11/01/2006-10/31/2008  5%
Subcontract through Memorial Hermann
Title: Botulinum Toxin A Treatment of Detrusor External Sphincter Dyssynergia During Early SCI
Allergan, Inc., Smith (PI) 12/18/2006-12/17/2008 2%

Title: Preclinical Assessment of Botulinum Toxin (BTX-A) And Botulinum Toxin B (BTX-B) Following Bladder Injection in Rats

Foundation Award, Smith (PI) 01/01/2007-12/31/2007 2%

Hamill Foundation

Title: Use of Botulinum Toxin to Examine Mechanisms of Urinary Incontinence Following Radical Prostatectomy

Protocol 191622-515-00 Smith (PI) 04/01/2007-03/31/2009 2%

Allergan, Inc.

Title: A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of the Safety and Efficacy of Repeat Treatment with Two Dose Levels of BOTOX (Botulinum Toxin Type A) Purified Neurotoxin Complex Followed by a Treatment with BOTOX in Patients with Urinary Incontinence Due to Neurogenic Detrusor Overactivity

DK60810 Smith (PI) 07/01/2007-06/30/2008 2%

NIDDK/Allergan

Title: Intraprostatic Injection of Botulinum Toxin for the Management of Benign Prostatic Hyperplasia: A Randomized Phase II Trial

Career Development Award, Smith (PI) 05/01/2008-12/15/2011 75%

Department of Veterans Affairs

Title: Role of Central ATP in Bladder Overactivity

Rising Star in Urology Program (PI) 05/01/2008-05/01/2011

Astellas/AUA Foundation

Title: Role of Central ATP in Bladder Overactivity

B. National Scientific Participation:

1. Journal Editorial Boards: Not Applicable

2. Review Panels:

Reviewer, Neurourology & Urodynamics
Reviewer, Journal of Urology
Reviewer, Urology
Reviewer, American Journal of Physiology

3. Professional Societies/Elected Positions:

Member, American Urological Association
Member, American Association of Clinical Urologists
Member, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction
Member, Texas Urologic Society
Member, Special Operations Medical Association
Member, South Central Section of the American Urological Association
4. **Invited Lectures, Presentations, Research Seminars:**


3. “Urolume and Artificial Urinary Sphincter Placement in Men with Urethral Strictures and Urinary Incontinence.” AUA South Central Section, Cancun, Mexico, 1998.


51. Panelist, “Neuromodulation and the Non-Neurogenic Bladder. Where Should it Be in the Algorithm for the Overactive Bladder.” Update in Urogynecology and Female Urology, The University of Texas Medical School of Houston, Houston, TX, February 2008.


60. Faculty, “The Use of Botulinum Toxin in the Treatment of Lower Urinary Tract Disorders and Pelvic Floor Dysfunction” and “Pudendal Nerve Stimulation for the Treatment of IC/Chronic Pelvic Pain.” 18th Innovations in Urologic Practice. Houston, TX, October 15-16, 2010.


69. Faculty, “Botulinum Toxin and BPH: Results of the MIST Trial” and “Management of Refractory OAB.” 19th Innovations in Urologic Practice, Santa Fe, NM, October 5-7, 2012.


C. Publications:

1. Full Papers:

   a. Published in Peer-Reviewed Journals:


b. **Accepted or In Press:**

1. Scovell JM, Chan R, **Smith CP**: Transurethral use of a nephroscope significantly aids in the surgical management of an intrauterine device eroding into the bladder. Female Pelvic Med Reconstr Surg, accepted for publication Apr 2014.

2. **Other Full Papers:**

a. **Published Without Review by Peer Group:**


6. **Smith CP**: Botox (onabotulinumtoxinA) pivotal data. Botox (onabotulinumtoxinA) for the treatment of urinary incontinence due to neurogenic detrusor overactivity in patients who have an inadequate response to or are intolerant of an anticholinergic. Urology Times (Supplement), Dec 2012.

b. **In Preparation**: Not Applicable

3. **Abstracts Given During the Last Three Years:**


4. **Books:**

   a. **Complete Books Written:**


   b. **Books Edited:** Not Applicable

   c. **Book Chapters Written:**


**5. Other Works Communicating Research Results to Scientific Colleagues**: Not Applicable

**6. Other Works Communicating Research Results to General Public**: Not Applicable
III. TEACHING INFORMATION

A. Didactic Course Work:

1. Courses Taught at BCM Within the Primary Department:

   2002-Present Reading Group Mentor

2. Courses Taught at BCM External to the Primary Department:

   2002-Present “Autonomic Pharmacology Lecture.” Baylor College of Medicine, Pharmacology lecture to medical students on quarterly basis, Houston, TX

   2009-Present Instructor, Surgical Subspecialty Lectures, Medical Students, Baylor College of Medicine, Houston, TX

3. Courses Taught at Other Institutions While at BCM:


B. Curriculum Development Work:

   2003-2006 Baylor College of Medicine Curriculum Competency Subcommittee Member

   2002-Present Reading Group for Urology Residents

   2006-Present Residency Review Committee

C. Non-Didactic Teaching While at BCM:

1. Resident Training:

   1-Year Laboratory Training for 4th Year Urologic Residents

   2002 H. Henry Lai, M.D.
   2003 Mohit Khera, M.D.
   Vijaya Vemulakonda, M.D.
   Jeffrey Evans, M.D.
   2004 Kimberley Takahashi, M.D.
   2005 Elias Hsu, M.D.
   2006 Desiderio Avila, M.D.
   John Boon, M.D.
   2007 Zaneta Romain, M.D.
   Kenneth Yun, M.D.
   Samson Shen, M.D.
   Melina McCarty, M.D.
2003 H. Henry Lai, M.D., received a second place of the Lapides Award for his work on role of caveoline in the bladder function

2005 H. Henry Lai, M.D., received a 1-year AFUD fellowship for pursuing 1 year research in the Neurourology Laboratory in the Scott Department of Urology

2006 Elias Hsu, M.D., received the Arnold’s award as the best resident researcher in 2005-2006

2006 Mohit Khera, M.D., received the AFUD fellowship and Pfizer Award for 2006-2007

2004-Present Faculty Mentor for Medicine residents participating in the Woman’s Health Initiative for LACE program

2. Clinical Fellow Training:

2003-2006 Rebecca McCrery, M.D., Urogynecology Fellow in Neurourology and Female Urology

2004-2007 Phillip P. Smith, M.D., Urogynecology Fellow in Neurourology and Female Urology


2005-2008 Eric Hurtado, M.D., Urogynecology Fellow in Neurourology and Female Urology

3. Research Fellow Training:

1-Year Laboratory Training:

2004 Rebecca McCrery, M.D.
2005 Phillip P. Smith, M.D.
Zachary Zuniga, M.D.
H. Henry Lai, M.D. (AFUD Fellowship)
2006 Eric Hurtado, M.D.
Mohit Khera, M.D. (AFUD Fellowship)

4. Graduate Student Training:

2005-2006 H. Henry Lai, M.D., AFUD Scholar Fellowship
2006-2007 David Gangitano, Ph.D., Postdoctoral Fellow
2007-2008 Alvaro Munoz, Ph.D., Postdoctoral Fellow

5. Medical Student Training:

1-2 Months Research Laboratory Rotation:

2003 Rahmat Ali (July-August - 2 months), University of Karachi
Christopher P. Smith, MD, MBA, MSS
September 2, 2014
Page 22

2004
Jennifer Sung 2nd year (March, 1 month), Baylor College of Medicine (BCM)
Vairavan Subramanian 4th year (April-May, 2 months), Baylor College of Medicine
Tulika Garg 4th year (June-July, 2 months), Baylor College of Medicine
Brenda Tharian 2nd year (July, 1 month), Texas A&M

2005
Catherine Chen 2nd year (March 1-30) BCM
Joe Kuebeker 3rd year (April 1-May 10) BCM
Samir Shirodkar 3rd year (May 11-June 30) BCM
Philip Ho 3rd year (Aug 29-Sep 23) BCM

2006
David Goldfarb 3rd year (January 3-31), BCM
Jeff Walter 3rd year (March 2-28), BCM

D. Lectures: Included in II. B.4. Invited Lectures, Presentations, Research Seminars
   1. International: See II. B.4. Invited Lectures, Presentations, Research Seminars
   3. Regional: See II. B.4. Invited Lectures, Presentations, Research Seminars
   4. Local: See II. B.4. Invited Lectures, Presentations, Research Seminars

E. Visiting Professorships: Not Applicable

IV. MEDICAL AND SERVICE INFORMATION

A. Patient Care Responsibilities at BCM and/or its Affiliated Institutions:
   1. Department-wide: Not Applicable
   2. Section or Specialty: Not Applicable

B. Clinical Laboratory Responsibilities at BCM: Co-Director of Neuourology Laboratory

C. National Education or Voluntary Health Organization Participation:
   2003-2005 Board Member, Interstitial Cystitis United of Texas
   2005-Present Medical Advisory Board Member, Interstitial Cystitis United of Texas
   2002-Present Presentations on Voiding Dysfunction for local Multiple Sclerosis Societies, ICU of Texas, and Parkinson Foundation of Harris County
   2002-Present Presentations on Voiding Dysfunction at Brentwood Baptist Church, Houston, TX

D. Administrative Assignments at BCM:
   1. Department Administration/Committees:
      2005-Present Education Committee
   2. College Administration/Committees:
      2003-2006 Baylor Admissions Committee
      2003-2006 Baylor Curriculum Competency Subcommittee
      2006-Present Baylor Residency Review Committee
2004-Present  Baylor Woman’s Health Initiative Rotation for Internal Medicine Residents
2011-Present  The Institutional Review Board for Human Subject Research for BCM and Affiliated Hospitals: Board 2
2012-Present  Urology Safety Officer, Baylor ACE Council

E. **Other Pertinent Information Not Given Above:**

1. **Hospital Appointments:**
   - 2004-Present  The Methodist Hospital Main Operating Room Subcommittee, Houston, TX

2. **Consultant Appointments:**
   - 1. Allergan USA, Inc.: Member, Advisory Board

3. **TV Interviews:**
   - 1. “Use of Botulinum Toxin for OAB and Interstitial Cystitis.” Channel 2 TV, Houston, TX, April 2003.
   - 2. “Botox for OAB and Interstitial Cystitis.” Baylor TV Healthline, Baylor College of Medicine, Houston, TX, April 2003.

4. **Media - Internet:**
A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)
SC110198; SCIRP-CTA-R
W81XWH-12-1-0549

PI: Christopher P. Smith, MD
Org: Baylor College of Medicine  Award Amount: 904,516.00

Study/Product Aim(s)
• Screen, enroll, and treat 36 patients randomized to two treatment groups
• Evaluation of biomarkers pretreatment and during follow up

Approach
FDA IND, BCM IRB, and MEDVAMC approvals were granted. HPRO approval with funding notice was received March 2013. IRB/VA approvals for advertising were approved. Continue to recruit at MEDVAMC and start recruitment at The Institute of Rehabilitation and Research (TIRR), located in the Texas Medical Center by end of 2014.

Goals/Milestones

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BOTOX Injection Pattern Diagram

Accomplishment: Letters (257) have been mailed to patients. One subject consented but lost to follow-up prior to treatment. 130 charts have been reviewed with no patients accrued. Dr. Smith has completed training to acquire certification at new site, TIRR Memorial Hermann and is awaiting committee approval. Then patient accrual at TIRR can commence.

Comments/Challenges/Issues/Concerns
• Delayed enrollment due to BCM IRB/VA and TIRR/Memorial Hermann approvals

Budget Expenditure to Date
Projected Expenditure: $85,000
Actual Expenditure: $82,693

Updated: October 2014