**Cinnamon Bark, Water-Soluble Cinnamon Extract, and Metformin as Initial Treatment for Type 2 Diabetes Mellitus: A Randomized, Controlled Trial.**

Paul Crawford, MD

Clinical Investigation Program
Mike O'Callaghan Federal Medical Center
4700 Las Vegas Blvd North
Nellis AFB, NV 89191

Approved for public release; distribution is unlimited.

No results are available. The study proved unworkable due to the lack of subject recruitment and is being closed.

Jill Clark
(702) 653-3298
**FINAL REPORT ACKNOWLEDGEMENT:**

**Acknowledgement Date:** 14 Dec 16

**Principal Investigator:** Col Paul Crawford/NELLIS AFB

**IRB Reference Number:** FWH20110004H

**Protocol Title:** “Cinnamon Bark, Water-Soluble Cinnamon Extract, and Metformin as Initial Treatment for Type 2 Diabetes Mellitus: A Randomized, Controlled Trial.”

1. Your Final Report submitted 9 Dec 16 for the study referenced above, was reviewed by the IRB Chairperson or designated reviewer, acknowledged on 14 Dec 16 and will be reported to the IRB for information. Final Reports are forwarded to SGE-C for their information.

This study was due to expire 26 Jul 17. This study is **now closed** as of 14 Dec 16.

**Documents Reviewed:** Final Report, Form A-1 Principal Investigator's Signature Sheet (Reason Closed: U-Unworkable) FOLLOW-UP CLOSED

2. **Please note:** By submitting your final report you indicated that you and your research team will no longer have access to identifiable information for the purposes of this research study. Best practice would suggest that you have already, returned any unused test articles or funding, forwarded all blood or tissues samples (if any) as appropriate for your protocol, and contacted all of your research team, all engaged institutions, clinics, supporting organizations, funding agencies, etc. regarding the cessation of all research activity on this study.

3. **IAW AFI 40-402 Inactivation of this study will be reported to AFMSA/SGE-C, and documented in a subsequent IRB minutes to the 24 Jan 17 IRB Meeting.**

4. If you have any questions, please contact Norma Ibarra at (210) 292-5819 or norm.a.ibarra3 ctr@mail.mil. Please include your project title and reference number in all correspondence or inquiries.

NORMA IBARRA
Clinical Research Coordinator
SGVUS (Protocol Support)
(210) 292-5819

*Warrior Medics – Mission Ready – Patient Focused*
**Title:** Cinnamon bark, water-soluble cinnamon extract, and Metformin as initial treatment for Type 2 diabetes mellitus: A randomized, controlled trial.

**IRB #:** FWH20110004H

<table>
<thead>
<tr>
<th>Principal Investigator (PI)</th>
<th>Rank / Civ Rating</th>
<th>Branch</th>
<th>AD/DoD Civ/ Ctr/Civilian</th>
<th>Dept/Base</th>
<th>Phone #</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paul Crawford, MD</td>
<td>COL</td>
<td>USAF</td>
<td>AD</td>
<td>FMR/Nellis</td>
<td>(702) 653-3298</td>
<td><a href="mailto:Paul.crawford@us.af.mil">Paul.crawford@us.af.mil</a></td>
</tr>
</tbody>
</table>

**Purpose of Study:**
The purpose of this study is to assess whether Cinnamon bark or water-soluble cinnamon is an effective nutraceutical for the initial treatment of diabetes when compared to standard therapy of Metformin.

**Results from Study:**
No results are available. The study proved unworkable due to the lack of subject recruitment and is being closed.

**How May your Findings Benefit the Air Force?**
No results are available. The study proved unworkable due to the lack of subject recruitment and is being closed.

**Reason for Closure:**
- [ ] Objectives of the study were met
- [ ] Study is no longer necessary (outmoded, outdated, science has changed)
- [ ] Closed by sponsor
- [x] Unworkable (explain in problems section)
- [ ] Withdrawn
- [ ] Other

**Consent Process:**
- [x] Used a Request for Waiver of Written ICD and a Request for Waiver of HIPAA Authorization.
- [x] Yes
- [ ] No
- [ ] Yes
- [ ] No
- [x] Yes
- [ ] No
- [x] Yes
- [ ] No
- [ ] Yes
- [ ] No

**Status of Subjects:**
- Subject’s participation is as expected.
- [ ] Yes
- [x] No
- [ ] Yes
- [ ] No

**Number of Subjects Entered into the Study:**

<table>
<thead>
<tr>
<th>Number of Subjects at MOFMC</th>
<th># Approved to Enroll</th>
<th># Enrolled Since Last Report</th>
<th>Withdrawals To-Date</th>
<th>TOTAL Enrolled To-Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>309</td>
<td>2</td>
<td>3</td>
<td>25</td>
</tr>
</tbody>
</table>

**Office of Research Protocol Support Use Only:**

- [ ] PI
- [ ] Co-PI
- [ ] Auth AI

**Received on:** [ ]
**Initials:** [ ]
**Report Expiration Date:** [ ]
**Scheduled for IRB:** [ ]

**Version:** 3 November 2016
Cinnamon bark, water-soluble cinnamon extract, and Metformin as initial treatment for Type 2 diabetes mellitus: A randomized, controlled trial.

Summary of Patient Withdrawals from the Study:

<table>
<thead>
<tr>
<th>Date of Withdrawal</th>
<th>Withdrew Due To Screening Failure?</th>
<th>Reason for Patient Withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/18/15</td>
<td>NO</td>
<td>012: Elevated liver enzymes suggest potential alcohol abuse</td>
</tr>
<tr>
<td>05/20/16</td>
<td>NO</td>
<td>019: Side effects from Metformin (Diarrhea)</td>
</tr>
<tr>
<td>07/14/16</td>
<td>NO</td>
<td>020: Experience leg swelling</td>
</tr>
</tbody>
</table>

Summary of Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) Events: NONE

Summary of Serious Adverse Events (SAE): NONE

Summary of Protocol Deviations:

<table>
<thead>
<tr>
<th>Date Deviation Reported</th>
<th>Local or External?</th>
<th>Description of Protocol Deviation and Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/07/15</td>
<td>Local</td>
<td>Subject 010 subject signed an expired copy of the Informed consent document. The Informed Consent expired on 9/24/14 and the subject signed it on 9/25/14.</td>
</tr>
</tbody>
</table>

Summary of Complaints About the Study: NONE

Amendments/Changes to Protocol, Informed Consent, or Investigator’s Brochure:

<table>
<thead>
<tr>
<th>Amendment #</th>
<th>Date Approved</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>22 Mar 11</td>
<td>SGE-C requested changes to the protocol</td>
</tr>
<tr>
<td>2</td>
<td>6 Apr 11</td>
<td>SGE-C requested changes to the protocol and ICD</td>
</tr>
<tr>
<td>3</td>
<td>28 Jun 11</td>
<td>Changes to the protocol and ICD. Added an AI, 90 day study calendar and diet and exercise questionnaire.</td>
</tr>
<tr>
<td>4</td>
<td>24 Jan 12</td>
<td>Research protocol, ICD, external support appendix and investigational new drug appendix (SGEC and FDA IND recommended changes, PI Letter dated 15 Dec 2011)</td>
</tr>
<tr>
<td>5</td>
<td>24 Apr 12</td>
<td>Added changes to the protocol and ICD in response to FDA IND suggestion. Added exclusion criteria for liver disease, alcoholism and NYHA Class III and IV congestive heart failure, added one week lab visit, fasting comprehensive metabolic panel, self-monitoring blood glucose statement and added risk for hypoglycemic episodes.</td>
</tr>
<tr>
<td>6</td>
<td>18 Dec 12</td>
<td>Add and remove an AI</td>
</tr>
<tr>
<td>7</td>
<td>8 Jan 13</td>
<td>Change contractor information for an RA</td>
</tr>
<tr>
<td>8</td>
<td>19 Feb 13</td>
<td>Update advertisement flyer</td>
</tr>
<tr>
<td>9</td>
<td>4 Apr 13</td>
<td>Add side effects document to be given to subjects at time of medication dispensing.</td>
</tr>
<tr>
<td>10</td>
<td>25 Feb 14</td>
<td>Add 2 AI’s 2 RA’s 2 Research monitors, remove 2 AIs and changes to the protocol and ICD</td>
</tr>
<tr>
<td>11</td>
<td>9 Jun 14</td>
<td>Remove 3 research team members, add one member, minor updates to the protocol, Form A2 and HIPAA</td>
</tr>
<tr>
<td>12</td>
<td>5 Aug 2014</td>
<td>Remove from the protocol and form A2: Tom Harris, Samantha Choudhury, and add Lisa Stammers. Also in the protocol to remove the line stating the patients will bring in remaining drug to determine adherence rate since we are not doing pill counts.</td>
</tr>
<tr>
<td>13</td>
<td>28 Oct 2014</td>
<td>Removal of an AI and revision of inclusion criteria.</td>
</tr>
<tr>
<td>14</td>
<td>19 Nov 15</td>
<td>Requesting personnel changes and changes to study diary and adding a new research monitor</td>
</tr>
</tbody>
</table>
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<p>| | | |</p>
<table>
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<tbody>
<tr>
<td>15</td>
<td>16 Nov 15</td>
<td>Requesting to make changes in the protocol and ICD</td>
</tr>
<tr>
<td>16</td>
<td>30 June 16</td>
<td>Requesting to add personnel, to make changes to the protocol, to make changes in the ICD, to make changes in the RAND 36 Item Questionnaire and updating HIPAA</td>
</tr>
</tbody>
</table>

**Status of Resources:**
All resources have been exhausted.

- The study used a drug that had an IND: Yes
- The drugs were inventoried and disposed of in accordance in hospital policy.
- The study used a device that had an IDE: No

**Describe the local investigator’s ongoing plan to protect the confidentiality of the research data:**
The research documents will be stored and destroyed in compliance with WHASC guidelines.

**Describe the local investigator’s plan to store the research records:**
The PI will keep an electronic copy of the informed consent documents and HIPAAs for at least 3 years after the study is complete. Once the study is closed, the WHASC IRB will be sent a digital copy for indefinite archiving.

**Publications and Presentations:** NONE

**Exceptional Achievements:** NONE

**CC:** Maj David Moss, Research Monitor (Primary), Maj Tristan Sevdy (Alternate)

**Attachments:**
1. Adverse Events Tracking Log
2. SAFE File Exchange of signed Informed Consent Documents/HIPAA
3. Form A-1, Multi-Purpose Signature Sheet