AWARD NUMBER: W81XWH-12-1-0429

TITLE: Vitamin E Supplementation in Burn Patients

PRINCIPAL INVESTIGATOR: Perenlei Enkhbaatar, MD., PhD.

CONTRACTING ORGANIZATION: University of Texas Medical Branch
Galveston, TX 77555-1102

REPORT DATE: October 2015

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

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.
Our recent findings demonstrate that burn injury significantly depleted stores of vitamin E in adipose tissue of children by nearly 50% within one month of injury. The consequences of this severe and rapid depletion are unknown because adipose tissue alpha-tocopherol normally takes years to deplete. Our long-term goal is to improve the quality of life of the burn patient by preventing pathophysiology that may result from oxidative stress. The objectives of our proposal were to a) attenuate alpha-tocopherol depletion in burn patients by vitamin E supplementation, b) to prevent or reverse oxidative stress, c) to collect pilot data on the effect of vitamin E supplementation on lung function and impaired wound healing. We have administered vitamin E supplements to burn subjects for either days 1-15 or days 16-30 of the study (n= 21 per group, 16-85 years, ≥40% total body surface area burns) at the Blocker Burn Unit (BBU) at the University of Texas Medical Branch (UTMB) in Galveston, the Burn Intensive Care Unit at Memorial Hermann Hospital (BICU-MHH) in Houston, and the Parkland Health and Hospital System Burn Unit (PHHS-BU) in Dallas.
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>2</td>
</tr>
<tr>
<td>2. Keywords</td>
<td>2</td>
</tr>
<tr>
<td>3. Accomplishments</td>
<td>2</td>
</tr>
<tr>
<td>4. Impact</td>
<td>2</td>
</tr>
<tr>
<td>5. Changes/Problems</td>
<td>3</td>
</tr>
<tr>
<td>6. Products</td>
<td>3</td>
</tr>
<tr>
<td>7. Participants &amp; Other Collaborating Organizations</td>
<td>3</td>
</tr>
<tr>
<td>8. Special Reporting Requirements</td>
<td>3</td>
</tr>
<tr>
<td>9. Appendices</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
1. Introduction:
Our recent findings demonstrate that burn injury significantly depleted stores of vitamin E in adipose tissue of children by nearly 50% within one month of injury. The consequences of this severe and rapid depletion are unknown because adipose tissue alpha-tocopherol normally takes years to deplete. Our long-term goal is to improve the quality of life of the burn patient by preventing pathophysiology that may result from oxidative stress. The objectives of our proposal were to a) attenuate alpha-tocopherol depletion in burn patients by vitamin E supplementation, b) to prevent or reverse oxidative stress, c) to collect pilot data on the effect of vitamin E supplementation on lung function and impaired wound healing. We have administered vitamin E supplements to burn subjects for either days 1-15 or days 16-30 of the study (n= 21 per group, 16-85 years, ≥40% total body surface area burns) at the Blocker Burn Unit (BBU) at the University of Texas Medical Branch (UTMB) in Galveston, the Burn Intensive Care Unit at Memorial Hermann Hospital (BICU-MHH) in Houston, and the Parkland Health and Hospital System Burn Unit (PHHS-BU) in Dallas.

2. Keywords:
burn, smoke inhalation, vitamin E, patients, oxidative stress, pulmonary function, ICU days

3. Accomplishments:
a. What were the major goals and objectives of the project?
Our central hypothesis is that the administration of high doses of alpha-tocopherol will prevent or restore levels of vitamin E in adipose tissue and reverse the oxidative state present in burn patients. We have proposed to complete 42 burned adult subjects at the end of three years at three sites across Texas.

b. What was accomplished under these goals?
All three sites have collectively enrolled 24 subjects into the clinical trial.

c. What opportunities for training and professional development did the project provide?
Dr. Linda Sousse has learned oxidative stress marker analyses for the plasma and urine samples. Beginning 1-Oct-2014 as a junior faculty member, she now has her own lab at the Shriners Hospitals for Children where she will be analyzing samples for oxidative stress markers with her own HPLC.

d. How were the results disseminated to communities of interest?
The results will be published in an abstract form at a major critical care meeting such as the American Burn Association or Shock, and its results will be published in a high impact journal such as the Society for Free Radical Biology in Medicine. Additionally, the Chiefs-of-Staff are intricately involved in this project and will inform additional sites of its findings.

e. What do you plan to do during the next reporting period to accomplish the goals and objectives?
The primary goals for the next period include enrolling the final subjects at each site until March 2016, and then we will begin sample analyses. Additionally, the Site PIs and the site study coordinators will meet at least once every 4 months to discuss the status of the ongoing study and future directions.

4. Impact:
a. The development of the principal discipline(s) of the project;
We anticipate that this research will yield the following outcomes: A) improve our understanding of the metabolism of alpha-tocopherol in thermally injured patients, and B) demonstrate the mechanism by which vitamin E administration reverses the oxidative stress induced by burn injury. We anticipate that vitamin E supplements will prevent vitamin E depletion, reduce oxidative stress, attenuate the development of lung dysfunction and impaired wound healing, reduce hospital stay, and improve the quality of life of burn patients.

b. Other disciplines;
Our outcomes have an important positive impact because they will lay the foundation for the development of effective, safe, and economic therapeutic interventions to treat burn injury-associated metabolic abnormalities.
c. Technology transfer; or
Not Applicable

d. Society beyond science and technology
Not Applicable

5. Changes/Problems
a. Changes in approach and reasons for change.

None

b. Actual or anticipated problems or delays and actions or plans to resolve them.

Because of low enrollment over the past three years, we have requested and have been approved for a no cost extension until September 2016. We will continue to enroll patients until March 2016.

c. Changes that have a significant impact on expenditures.

None

d. Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.

None

6. Products
a. Publications, conference papers, and presentations;
The results will be published in an abstract form at a major critical care meeting such as the American Burn Association or Shock, and its results will be published in a high impact journal such as the Society for Free Radical Biology in Medicine.

b. Website(s) or other Internet site(s);
Not Applicable

c. Technologies or techniques;
Not Applicable

d. Inventions, patent applications, and/or licenses; and
Not Applicable

e. Other products.
Not Applicable

7. Participants & Other Collaborating Organizations
a. University of Texas Medical Branch Blocker Burn Unit (UTMB BBU) in Galveston
b. Burn Intensive Care Unit at Memorial Hermann Hospital (BICU-MHH) in Houston
c. Parkland Health and Hospital System Burn Unit (PHHS-BU) in Dallas

8. Special Reporting Requirements
None

9. Appendices
None