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TITLE:

Vitamin E Supplementation in Burn Patients

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CONTRACTING ORGANIZATION:

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The fund was awarded to the University of Texas Medical Branch (UTMB) on 27-September 2012. This multi center clinical study is approved to be performed at three sites in Texas--(1) The University of Texas Medical Branch Blocker Burn Unit in Galveston; (2) Burn Intensive Care Unit at Memorial Hermann Hospital in Houston; and (3) Parkland Health and Hospital System Burn Unit in Dallas. UTMB. In a Year 1, we have opened the accounts for use at all 3 sites. The all three sites had institutional IRB and DoD HRPO protocol approvals except the site at Dallas that submitted HRPO for approval. In a Year 1, we have also hired all required personnel at 3 sites who will perform the study. We have also submitted an amendment to change PI—initial Principal Investigator Dr. Traber passed away and received an approval. Dr. Enkhbaatar assumed a role of new PI. The subcontracts have been established between the sites and the funds were distributed accordingly. The sites at the Galveston and Houston ordered all supplies necessary for the study, including vitamin E. All personnel were properly trained and the details of the study, including sample labeling and shipment were discussed and standard of operation was created. Investigators and study coordinators at all sites had met multiple times, discussing the details on the patient recruitment and study design. Dr. Michael Kinsky was selected as a study Monitor. The sites at Galveston and Houston started enrolling patients and we have completed 9 subjects out of proposed 42 subjects for 3 years.					
15. SUBJECT TERMS Vitamin E deficiency in burn patients and supplementation					
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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, $\geq 40\%$ 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?

1. PHHS-BU has obtained IRB and HRPO approval on 15-Apr-2013, and the site has enrolled 2 subjects. Dr. Linda Sousse (Co-Investigator and Study Coordinator) has visited the site to ensure that all sample collection is consistent at all sites. The site has been educated properly.

2. The BBU at UTMB has completed 12 subjects, while the BICU-MHH has completed 4 subjects total.

c. What opportunities for training and professional development did the project provide?

Dr. 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.

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, and more importantly, 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.

None

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