

AWARD NUMBER: W81XWH-13-2-0080

TITLE: Study of Tranexamic acid during Air Medical Prehospital transport (STAAMP) trial

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14. ABSTRACT Multi-center, prospective, randomized, blinded, controlled interventional trial focusing on patients with concern for bleeding who are transported via air medical transport to definitive care.						
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1. INTRODUCTION:

- The primary hypothesis is that the prehospital infusion of tranexamic acid in patients at risk for bleeding will reduce the incidence of 30-day mortality. The secondary hypotheses include that prehospital tranexamic acid will reduce the incidence of hyperfibrinolysis, acute lung injury, multiple organ failure, nosocomial infection, mortality, early seizures, pulmonary embolism and early resuscitation needs, reduce or prevent the early coagulopathy as demonstrated by improving presenting INR and rapid thromboelastography parameters, reduce the early inflammatory response, plasmin levels, leukocyte, platelet and complement activation, and determine the optimal dosing of tranexamic acid post-injury.

2. KEYWORDS:

- Prehospital; Tranexamic acid

3. OVERALL PROJECT SUMMARY: Summarize the progress during appropriate reporting period (single annual or comprehensive final). This section of the report shall be in direct alignment with respect to each task outlined in the approved SOW in a summary of Current Objectives, and a summary of Results, Progress and Accomplishments with Discussion. Key methodology used during the reporting period, including a description of any changes to originally proposed methods, shall be summarized. Data supporting research conclusions, in the form of figures and/or tables, shall be embedded in the text, appended, or referenced to appended manuscripts. Actual or anticipated problems or delays and actions or plans to resolve them shall be included. Additionally, any changes in approach and reasons for these changes shall be reported. **Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) requires review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.**

- University of Utah Site Initiation Visit (SIV) conducted on 03-OCT-2016.
- University of Pittsburgh Coordinating Center received IRB approval for protocol modification v1.9 on 18-OCT-2016.
- An investigator teleconference was held 19-OCT-2016 with UTHSCSA; investigator and coordinators were present.
- University of Pittsburgh Site received IRB approval to increase number of subjects at site on 21-OCT-2016.
- First Interim Monitoring Visit at UTHSCSA held on 07-NOV-2016.
- University of Pittsburgh Coordinating Center received IRB approval for protocol modification v2.1 on 15-DEC-2016.
- University of Utah Site received IRB approval for protocol modification v1.7 on 21-DEC-2016.
- University of Pittsburgh Site received IRB approval for protocol modification v2.1 on 22-DEC-2016.
- University of Texas San Antonio site received IRB Annual Renewal approval on 10-JAN-2017.
- Protocol version 2.1 distributed to participating sites on 11-JAN-2017.
- University of Arizona site received IRB approval for protocol modification v2.1 on 18-JAN-2017.
- University of Texas San Antonio site received IRB approval for protocol modification v2.1 on 27-JAN-2017.
- An investigator teleconference was held 26-JAN-2017 with UTHSCSA; investigator and coordinator were present.

- An investigator teleconference was held 30-JAN-2017 with University of Arizona; investigator and coordinator were present.
- First Interim Monitoring Visit at University of Arizona held on 02-MAR-2017.
- University of Utah site received IRB approval for protocol modification v2.1 on 15-MAR-2017.
- University of Arizona IRB enrollment suspension was lifted on 30-MAR-2017.
- An investigator teleconference was held 01-MAY-2017 with University of Arizona; investigator and coordinators were present.
- University of Pittsburgh Site received IRB approval for Protocol version 2.2 on 02-MAY-2017.
- University of Pittsburgh Coordinating Center received IRB approval for Protocol version 2.2 on 17-MAY-2017.
- Second Interim Monitoring Visit at University of Texas San Antonio was held on 23-MAY-2017.
- University of Pittsburgh Coordinating Center received IRB Annual Renewal approval on 06-JUN-2017.
- First Interim Monitoring Visit at University of Utah held on 06-JUL-2017.
- University of Utah site received IRB Annual Renewal approval on 19-JUL-2017.
- Protocol version 2.2 distributed to participating sites on 28-JUL-2017.
- University of Pittsburgh site received IRB Annual Renewal approval on 03-AUG-2017.
- UTHSCSA received IRB approval for Protocol v2.2 on 04-AUG-2017.
- University of Arizona Site received IRB approval for Protocol v2.2 on 21-AUG-2017.
- STAAMP Investigator Meeting was held at AAST on 13-SEP-2017, Investigators from all sites were present. Items discussed:
 - o Low recruitment
 - o Missed enrollments (retraining scenarios were provided and are currently being converted into a quiz for distribution to the pre-hospital crews).

4. KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research. Project milestones, such as simply completing proposed experiments, are not acceptable as key research accomplishments. Key research accomplishments are those that have contributed to the major goals and objectives and that have potential impact on the research field.

- Secretary of Defense Approval for Arizona performing site was received on 05-DEC-2016.
- University of Arizona site commenced enrollment on 03-JAN-2017.
- Secretary of Defense Approval for Utah performing site was received on 25-JAN-2017.
- No Cost Extension (NCE) approval received on 16-FEB-2017.
- University of Utah site commenced enrollment on 25-FEB-2017.
- 01-AUG-2017 FDA agrees to adding Heritage 1000 mg/10 mL; NDC 23155-166-31 as an additional formulation if needed.
- 23-AUG-2017 received permission from the FDA to allow administration of the study product via intraosseous access (IO) if the IO access was obtained due to a clinical need per standard of care.

5. CONCLUSION: Summarize the importance and/or implications with respect to medical and /or military significance of the completed research including distinctive contributions, innovations, or changes in practice or behavior that has come about as a result of the project. A brief description of future plans to accomplish the goals and objectives shall also be included.

- First Interim Analysis expected to be reached during the 4th quarter of 2017.

- Due to low enrollment at participating sites, we are considering an additional participating site(s).

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

- a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry shall include the author(s), article title, journal name, book title, editors(s), publisher, volume number, page number(s), date, DOI, PMID, and/or ISBN.

(1) Lay Press: ***Nothing to report***

(2) Peer-Reviewed Scientific Journals: ***Nothing to report***

(3) Invited Articles: ***Nothing to report***

(4) Abstracts: ***Nothing to report***

- b. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

- ***Nothing to report***

7. INVENTIONS, PATENTS AND LICENSES: List all inventions made and patents and licenses applied for and/or issued. Each entry shall include the inventor(s), invention title, patent application number, filing date, patent number if issued, patent issued date, national, or international.

- ***Nothing to report***

8. REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. This list may include development of prototypes, computer programs and/or software (such as databases and animal models, etc.) or similar products that may be commercialized.

- ***Nothing to report***

9. OTHER ACHIEVEMENTS: This list may include degrees obtained that are supported by this award, development of cell lines, tissue or serum repositories, funding applied for based on work supported by this award, and employment or research opportunities applied for and/or received based on experience/training supported by this award.

- ***Nothing to report***

For each section, 4 through 9, if there is no reportable outcome, state "Nothing to report."

10. REFERENCES:N/A

11. APPENDICES: N/A

NOTE:

TRAINING OR FELLOWSHIP AWARDS: N/A

- *Nothing to report*

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: N/A

MARKING OF PROPRIETARY INFORMATION: N/A