

AWARD NUMBER: W81XWH-13-2-0080

TITLE: Study of Tranexamic Acid During Air
Medical Prehospital Transport Trial
(STAAMP trial) - TACR

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15. SUBJECT TERMS Prehospital; Tranexamic acid						
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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: Provide a brief list of keywords (limit to 20 words).

- 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.**

- Interim Monitoring Visit at University of Arizona was held on 24-OCT-2017. University of Arizona received IRB Annual Renewal approval on 25-OCT-2017.
- Interim Monitoring Visit at University of Texas at San Antonio was held on 07-NOV-2017.
- University of Pittsburgh Coordinating Center received IRB approval for protocol modification v2.4 on 17-OCT-2017.
- University of Pittsburgh site received IRB approval for protocol modification v2.4 on 14-NOV-2017.
- University of Pittsburgh Coordinating Center received HRPO approval for protocol modification v2.4 on 15-NOV-2017.
- University of Pittsburgh site received HRPO approval for protocol modification v2.4 on 29-NOV-2017.
- University of Arizona site received IRB approval for change in PI on 27-NOV-2017.
- University of Arizona site received IRB approval for protocol modification v2.4 on 20-DEC-2017.
- An investigator/coordinator call was held on 16-JAN-2018.
- University of Texas at San Antonio received IRB Annual Renewal approval on 23-JAN-2018.
- University of Texas at San Antonio received HRPO Continuing Review approval on 08-FEB-2018.
- Interim Monitoring Visit at University of Utah was held on 06-MAR-2018.
- University of Pittsburgh Coordinating Center received IRB approval for protocol modification v2.5 on 22-FEB-2018.

- University of Pittsburgh Coordinating Center received IRB Annual Renewal approval on 30-MAY-2018.
- The University of Pittsburgh site received IRB approval for protocol modification 2.6 on 31-MAY-2018.
- The University of Utah received IRB Annual Renewal approval on 27-JUN-2018.
- Interim Monitoring Visit at University of Arizona was held on 17-APR-2018.
- The University of Pittsburgh Coordinating Center received IRB approval for protocol modification 2.6 on 12-JUL-2018.
- The University of Pittsburgh site received HRPO Continuing Review approval on 17-JUL-2018.
- University of Texas at San Antonio site received IRB approval for protocol modification 2.6 on 29-AUG-2018.
- STAAMP Investigator Meeting was held at AAST on 27-SEP-2018, Investigators from all sites were present.

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.

- First Interim Analysis reached on 08-OCT-2017.
- IDSMB first interim analysis meeting was held on 22-JAN-2018. The board unanimously voted for the study to continue without modification.
- Saline shortage resumed to normal production.
- Second Interim Analysis reached around 20-AUG-2018.
- IDSMB meeting was held on 07-SEP-2018. The board unanimously voted for the study to continue without modification.
- No Cost Extension (NCE) approval received on 27-SEP-2018.

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.

- University of Pittsburgh site expanded to ground; enrollment initiated at EAPS & Penn Hills on 02-JUL-2018.
- The University of Pittsburgh Coordinating Center decided to close the University of Arizona and Utah to accrual on 30-SEP-2018.
- Hold IDSMB Second Interim Analysis meeting in JAN-2019.

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:** List all references pertinent to the report using a standard journal format (i.e., format used in *Science*, *Military Medicine*, etc.).

- 11. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

NOTE:

TRAINING OR FELLOWSHIP AWARDS: For training or fellowship awards, in addition to the elements outlined above, include a brief description of opportunities for training and professional development. Training activities may include, for example, courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.

- ***Nothing to report***