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| AWARD NUMBER: | W81XWH-13-2-0080 |
| TITLE: | Study of Tranexamic Acid During Air Medical Prehospital Transport Trial (STAAMP Trial) |
| PRINCIPAL INVESTIGATOR: | Jason L. Sperry, MD, MPH |
| RECIPIENT: | Wilbur W. Malloy, MA, MLS(ASCP)SBB |
| REPORT DATE: | OCT-2019 |
| TYPE OF REPORT: | Annual |
| PREPARED FOR: | U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012 |

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 0704-0188*



| 1. REPORT DATE | 2. REPORT TYPE | 3. DATES COVERED |
|---|---|---|
| OCT-2019 | Annual Report | 30-Sep-2018 to 29-Sep-2019 |

**4. TITLE AND SUBTITLE**

Study of Tranexamic Acid During Air Medical Prehospital Transport Trial (STAAMP Trial)

**5a. CONTRACT NUMBER**

**5b. GRANT NUMBER**
W81XWH-13-2-0080

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**

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**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

University of Pittsburgh
Pittsburgh, Pennsylvania 15213

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland, 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**
Approved for Public Release; Distribution Unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

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

**15. SUBJECT TERMS**
Prehospital; Tranexamic acid

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
|---|---|---|---|---|---|
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | | USAMRMC |
| U | U | U | UU | | 19b. TELEPHONE NUMBER *(include area code)* |

**Table of Contents**

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.**

   - The University of Arizona received IRB Annual Renewal approval on 10-OCT-2018.
   - Close-out Visit at University of Arizona was held on 07-NOV-2018.
   - Close-out Visit at University of Utah was held on 28-NOV-2018.
   - The University of Texas at San Antonio received IRB Annual Renewal approval on 08-JAN-2019.
   - The University of Arizona site received HRPO Continuing Review approval on 30-JAN-2019
   - Close-out Visit at University of Texas at San Antonio was held on 08-FEB-2019.
   - University of Arizona site received IRB approval for change in PI on 20-MAR-2019.
   - The University of Texas at San Antonio site received HRPO Continuing Review approval on 26-MAR-2019.
   - The University of Pittsburgh Coordinating Center received IRB Continuing Review approval on 07-MAY-2019.
   - The University of Pittsburgh Coordinating Center submitted for HRPO Continuing Review on 22-MAY-2019.
   - The University of Pittsburgh site received IRB Continuing Review approval on 26-JUN-2019.
   - The University of Utah site received IRB Continuing Review approval on 27-JUN-2019.
   - The University of Pittsburgh site submitted for HRPO Continuing Review on 11-JUL-2019.
   - The University of Utah site submitted for HRPO Continuing Review on 22-JUL-2019.
   - University of Arizona site received HRPO approval for change in PI on 22-JUL-2019.

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.

- IDSMB second interim analysis meeting was held on 01-MAR-2019.
    - The board unanimously voted for the study to continue without modification.
- No Cost Extension (NCE) request was submitted on 21-AUG-201.

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.

- The University of Pittsburgh Coordinating Center decided to stop enrollment at external sites.
    - University of Arizona and University of Utah ceased enrollment on 31-OCT-2018.
    - University of Texas at San Antonio ceased enrollment on 30-NOV-2018.

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***

**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:** If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

**MARKING OF PROPRIETARY INFORMATION:** Data that was developed partially or exclusively at private expense shall be marked as "Proprietary Data" and Distribution Statement B included on the cover page of the report. Federal government approval is required before including Distribution Statement B. The recipient/PI shall coordinate with the GOR to obtain approval. REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE. It is the responsibility of the Principal Investigator to advise the GOR when restricted limitation assigned to a document can be downgraded to "Approved for Public Release." DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS. See term entitled "Intangible Property – Data and Software Requirements" and https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting for additional information.