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

PUBLIC DISCLOSURE

Disclosure includes “dissemination of information after the investigation is completed so that communities and scientific researchers are aware of the study’s results”.

Appropriate public disclosure includes:

- Clear statement that informed consent will not be obtained for any subjects
- Information about the study medications use including a balanced description of the risks and benefits
- Synopsis of the research protocol and study design
- How potential study subjects will be identified
- Participating sites/institutions
- Description of the attempts to contact a LAR
- Suggestions for opting out of the study

PUBLIC DISCLOSURE – PLANNED ACTIVITIES

Public disclosure will be done prior to enrollment and may continue throughout the study period and after the study has completed. The coordinating center will provide monthly updates regarding enrollment and other study updates during the duration of the study. Disclosure of study results will be made both locally and nationally. The study results will be announced on the Sponsor’s site as well as http://test.healthcare.utah.edu/staamp/.

In addition, we will involve the University of Utah PR group, who are responsible for the press release to release new information and updates to the study. Results can be distributed locally in emails to hospital personnel and community physicians, and on flyers available to visitors of study sites in the ED. The study results will also be disclosed through peer-reviewed journals, and presentations at national meetings.

Using several different channels of communication for public disclosure increases the likelihood of reaching more of the intended audiences. It also can increase repetition of the message, improving the chance that intended audiences will be exposed to it often enough to absorb it. For these reasons, we will use a combination of channels.
CONTACT OF A LAR OR FAMILY MEMBERS

The federal regulations for contact of a Legally Authorized Representative (21 CFR 50.24) state:

21 CFR 50.24
(a)(7)Additional protections of the rights and welfare of the subjects will be provided, including, at least:
(v) If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject’s family member who is not a legally authorized representative, and asking whether he or she objects to the subject’s participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
(b) The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.

PROCESS TO CONTACT AND OBTAIN INFORMED CONSENT FROM LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

Consent

A written consent and assent form that complies with the policies of local sites IRB must be developed and approved for STAAMP. It should include the following elements:

- Title of the protocol
- Name of the PI
- Study objectives and purpose
- Detailed description of the procedure and interventions
- Explanation of the responsibilities of the subject and of the family member(s) who act as proxy respondents during follow-up interviews
- Any foreseeable risks, anticipated benefits, available alternatives
- An explicit statement of confidentiality
- Non-compensation for participation
- Right to withdraw at any time
- Signature section
- Number to contact the PI or a member of the study team with any questions.

EFIC process and LAR Tracking

The definition of LAR is determined by local state regulations. LAR is typically defined as:

- Health-care agent
- Legal guardian or special guardian
- Next-of-kin: a close relative of the subject 18 years of age or older, in the following priority:
  - Spouse
  - Adult child (18 years of age or older)
  - Parent
  - Adult sibling (18 years of age or older)
  - Grandparent
Adult grandchild (18 years of age or older)

When more than one LAR is present, the closest relative, as defined above, should give consent. However, unless otherwise stated in local or state regulations, any of the above individuals are acceptable for LAR consent if others are not promptly available.

We will presumptively enroll eligible patients using the exception from informed consent (EFIC) process 21 CFR 50.24. EFIC does not obviate the need for patient or LAR consent. Subjects enrolled in STAAMP, or their legally authorized representatives (LAR) or family, are informed of the subject’s inclusion in the clinical investigation at the earliest possible opportunity. The study team is immediately notified of the arrival of treated subjects in the emergency department (ED). An on call study team member quickly responds to the ED to complete the subject enrollment. The subject (or LAR or family) is approached, and an informed consent process initiated as soon as possible.

LAR tracking will typically be a shared responsibility between the onsite social workers (or equivalent) and the study team. Each site PI and team will meet with their social workers (or equivalent) before the trial initiation to inform them of the STAAMP protocol and need for intensive LAR search. The site team should review the local protocol for LAR search and assure that it is sufficient (multiple methods for locating LAR and multiple attempts), and if not, recommend additional steps be put in place.

Once located, an LAR will be informed of the patient’s inclusion into the study and of the details and risks of the study. At that time, the LAR will be given the option to continue patient participation in the study, or to cease patient participation then or at anytime throughout the course of the study. If the LAR wants to continue the patient’s participation, an informed consent form signed by the LAR will be obtained. If an established LAR has given consent for the patient to be enrolled, other family members’ objections to inclusion will not result in the patient’s removal from the study. Once fully awake, the patient may consent to or decline continued participation in the study.

Using the Informed Consent CRF, the study team will document efforts to find the LAR. This will include contact person (Subject, LAR, Other), number of attempts, date and time and outcome of attempts. The tracking process should continue until consent or a withdrawal is obtained. The tracking process is complete once the LAR or participant has provided consent or has withdrawn. It is expected that LAR consent or withdrawal be obtained within the first 24 hours, except in rare circumstances (no LAR identified, LAR not available, patient identification is unknown, patient expires prior to consent being obtained, etc.).

For participants who expire prior to identifying an LAR or before LAR consent is obtained, consent should not be pursued further. However, once an LAR is located, they should be informed of the subject’s participation (per FDA requirements). The study team should document the conversation and keep a copy of the family notification letter (with return receipt).

In the rare case where no LAR consent is obtained and the participant remains incapable of consent at 1 month, documentation of the attempt process and condition of the participant will be recorded on the Informed Consent Log CRF. In these cases the final outcome will be discussed and approved by STAAMP leadership.

DESCRIPTION OF REFUSAL OF PARTICIPATION PROCEDURES (OPT-OUT)
As part of our community consultation and public disclosure activities, we have established national and local websites that will provide local contact information and instructions for refusing participation. We will also include this information on the brochures and posters for public disclosure. The study team will provide medical alert bracelets with the words to those individuals who decide to refuse participation in the trial.

Sponsor Website = http://acutecarereresearch.org/studies/current/study-tranexamic-acid-during-air-medical-prehospital-transport-staamp-trial
Local Website = http://test.healthcare.utah.edu/staamp/

DATA SAFETY MONITORING BOARD

An independent Data Safety Monitoring Board (DSMB) and will maintain the DSMB throughout the course of the clinical trial. The DSMB will provide ongoing evaluation of safety data as well as the overall conduct of the trial, as per institute guidelines.