WEBSITE CONTENT Template. Layout may be customized for site specific branding, images, contacts and flow.

"ABOUT" tab

1. What is the FASTEST Trial?

<<SITE location>> ***is conducting a research study of the emergency treatment of patients with bleeding in the brain also called intracerebral hemorrhage.***

<<SITE location>> has joined a partnership of over 100 other hospitals and mobile stroke units across North America and other countries in the world to study and determine if a medicine used to treat and prevent bleeding can also improve outcomes after a stroke caused by bleeding in the brain. Bleeding into the brain happens very rapidly and can be deadly. Over 40% of patients die and only 20% of survivors can care for themselves. There is no scientifically proven treatment for bleeding into the brain. The medicine is called Recombinant Factor VIIa. Participants in this study will receive either the medicine or a placebo that contains no active medications. The name of the study is rFVIIa for Acute hemorrhagic Stroke Administered at Earliest Time (FASTEST) Trial". It is sponsored by the National Institutes of Health.

2. Who will be included?

People who are 18 through 80 years old,
With spontaneous bleeding in brain,
And are able to be treated with study medication within 2 hours of stroke onset

3. Study groups:

Participants in this study are put at random, that is by chance, in one of 2 groups:
Placebo: placebo (no active ingredient) administered intravenously over 2 minutes
Recombinant Factor VIIa (rFVIIa): a protein that our body makes to stop bleeding at site of an injury to a blood vessel, will be administered intravenously over 2 minutes
*Both groups will receive standard medical care, including close management of blood pressure and care within intensive care unit

4. Benefits & Risks

Risks: rFVIIa may increase risk of developing life-threatening blood-clots. Blood-clots could cause heart attack, stroke, or serious lung problems. In other studies, this occurred rarely in persons given rFVIIa as compared to placebo
Benefits: Because the purpose of the study is to determine the effectiveness of rFVIIa compared to a placebo, it is not known whether or not you will benefit from being in this study. However, the knowledge gained from this study may help doctors learn more about what treatments are most effective for stroke.

5. How is FASTEST different than other studies?

Because of the severity of their brain injury, patients eligible for the FASTEST Trial will almost always be unable to say whether or not they wish to participate in the study. A special set of

government rules allow studies to include patients with an "exception from informed consent" under these circumstances. This is only allowed in life threatening circumstances, where the best strategy is unknown, when there is a potential benefit to participants, and when it is not possible to get consent from the patients' families or representatives before the study strategies need to begin. We are asking community members to think about this research and let us know what you think about the FASTEST study.

6. What if I don't want to participate in FASTEST?

If you do not wish to be enrolled into the FASTEST research study you must carry an "opt out card" at all times during the study enrollment period (approximately 3 ½ years beginning early 2021. Emergency teams and hospital staff will look for this card, the researchers will know not to enroll you in this study if they locate this card. If you would like a card, please contact the study team <<SITE specific>> go to the website listed below to print you own card, or fill out the Opt-Out Survey below. You may want to let your family know of your wishes to NOT participate in this study.

Printable Opt-Out Card:
site specific links

7. Where can I learn more about the FASTEST Trial?

Click to learn more about the FASTEST Trial through ClinicalTrials.gov
https://clinicaltrials.gov/ct2/show/NCT03496883
Click to learn more about StrokeNet: https://www.nihstrokenet.org/

"Survey" tab

We would like your feedback!
Take the survey in English: https://redcap.research.cchmc.org/surveys/?s=YALHC7W838
Take the survey in Spanish: https://redcap.research.cchmc.org/surveys/?s=Y8HMNK844R

OPTIONAL site specific → "Resources" tab

Presentation: powerpoint Fastest
Survey: Spanish/English
Opt-Out Resources/Instructions: <<Site specific information for opt out>>

OPTIONAL site specific → "Faculty" tab

- PI profile
- Sub-I profile

OPTIONAL site specific → "Events" tab

- We will list events as they are scheduled.

"Contact Us" tab

- Form: name, email, message
  Or
- Information to contact the study team