How can I share my opinions about the FASTEST research study?

Before the FASTEST research study starts, we are reaching out to communities to provide information, answer questions, and get community members' thoughts and feelings about this research study. You can call the study team to complete a one-on-one interview or ask for a survey about the research study. You can also visit the website below to find a survey link. Information about this research study will also be published in the media (for example, newspapers).

For more information, or to decline participation in this research study, please visit https://nihstrokenet.org/fastest/community-resources or contact our study staff at FASTEST@uc.edu.

What if I do not want to be included in this research study?

If you decide that you do not want to be included in the event you suffer a future intracerebral hemorrhage or ICH, contact us to request an Opt Out Card be sent to you. This card will state "FASTEST declined". Carrying this Opt Out Card at all times throughout the research study period (about 5 years), is your way of communicating your wishes in case you suffer an ICH and are unconscious. You may also want to let your family and legally authorized representatives know of your decision to decline inclusion in this research study so that they can communicate your wishes on your behalf. If you do not participate in this research study, you will receive the standard medical treatment at the hospital in your community.

Where can I learn more about the FASTEST research study?

Online at: https://nihstrokenet.org/fastest/community-resources

FASTEST

WHO TO CONTACT:

Attn: Dr. Broderick
NIH StrokeNet
260 Stetson Street, Suite 2300
Cincinnati, Ohio 45219

Email: FASTEST@uc.edu

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Learn about an emergency care research study of bleeding in the brain that may affect you or someone you know.

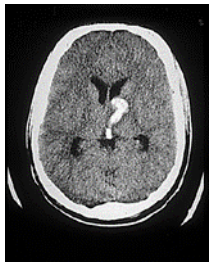
FASTEST

What Is A Brain Hemorrhage??

Brain Hemorrhage or intracerebral hemorrhage (ICH) is a type of stroke that accounts for more than 10% of the estimated 17 million strokes worldwide each year, or about 1,700,000 cases per year.

•More than 40% of patients die and only 20% of survivors are functionally independent after 6 months.

•The size of blood in the brain is the most important determinant of outcome. Most bleeding occurs within 2-3 hours.



•There is no scientifically proven effective treatment for ICH.

Who Could Be in the FASTEST Research Study?

- Patients between the ages of 18-80 years with spontaneous bleeding in their brain.
- Patients who are able to be treated with the research study medication within 120 minutes of stroke onset or last known well time.

What is the FASTEST research study?

The FASTEST research study is being done to determine if recombinant Factor VIIa (rFVIIa), a protein that our body makes to stop bleeding at the site of injury to a blood vessel, can slow bleeding in the brain and improve outcome. rFVIIa is approved for treatment of bleeding in patients who have inherited lack of clotting factors, but is not approved for treatment of ICH. Participants in the FASTEST research study are placed at random, that is by chance, into one of 2 groups. They have an equal chance of getting rFVIIa or placebo (no active ingredient). We do not know if rFVIIa is better than placebo for patients with bleeding in the brain. The results of the FASTEST research study will help doctors discover if rFVIIa improves outcome in patients with bleeding in the brain. Medical care otherwise will be identical for the two treatment groups, including close management of blood pressure and care within an intensive care unit.

What are potential benefits?

- If rFVIIa slows bleeding and improves outcome, participants may benefit from this research study.
- Future patients with bleeding in the brain may benefit from what is learned in the research study.

What are potential risks?

- Since rFVIIa helps stop bleeding by enhancing blood clotting, there is a risk of heart attacks, strokes due to blockage of brain arteries, and clots in the lung.
- There may be risks of breaches of confidentiality.

How is enrollment in FASTEST different from other research studies?

Patients usually must consent to be in a medical research study. The patients in this research study may be unable to consent for themselves. When a patient is unable to consent for themselves, consent to participate in the research study is sought from a family member or legal representative of a patient with ICH before including the patient in a research study. However, since the research study medication must be given within 2 hours of onset of symptoms, there might not be enough time to locate and talk to the person's family member or legal representative about the research study. If a family member or representative of the patient is not available to decide for the patient, a patient may be enrolled in this research study without consent. This is called Exception from Informed Consent (EFIC) for emergency research. Once the family member or legal representative is located, they will be asked to give their permission for the patient with ICH to continue in the research study. Because of this, we are asking community members to think about this research and let us know what you think about the study.

What is EFIC?

The U.S. federal government has created a set of special rules for Exception from Informed Consent for emergency research. EFIC can only be used when:

- The person's life is at risk, AND,
- The best treatment is not known, AND
- The study might help the person, AND
- It is not possible to get permission: from the person, because of his or her medical condition, nor from the person's guardian because there is a very short amount of time required to treat the medical problem.

Before researchers may do a study using EFIC, they must provide information about the study to the community and receive their feedback.