

10/28

Content Outline

Voiceover:

FASTEST is a study involving patients who experience spontaneous bleeding into the brain, also called intracerebral hemorrhage. This bleeding occurs when the tubes that supply blood to the brain, called blood vessels, break and blood accumulates in the brain. Bleeding into the brain happens very rapidly and can be deadly. Over 40% of patients die and only 20% of survivors are able to care for themselves. There is no scientifically proven treatment for bleeding into the brain.

FASTEST is a research study that tests whether a protein made by our bodies called recombinant factor viia may slow the bleeding and improve the outcome, if it is given to patients, either in the emergency department or a mobile stroke unit, within 2 hours of symptom onset.

Participants will be put into one of two groups, by chance, much like flipping a coin. Half will receive the recombinant factor VIIa and half will receive placebo, a non-active substance.

Everyone will receive the best standard medical care.

Since rFVIIa helps stop bleeding by encouraging a clot to form, there is a risk of heart attack, stroke due to blockage of brain arteries, and clots in the lung. In other studies, this occurred rarely in persons treated with rFVIIa as compared to placebo

The large majority of patients with brain hemorrhage are unresponsive and thus are unable to provide consent to participate in the study within the emergency two-hour response window.

If you or a family member is able to give consent you will always be asked. If you are enrolled in the study while unconscious you or your family member will be told as soon as possible. If necessary, you can opt out of enrollment in the study in advance.

Because this study is reliant on a quick response in an emergency situation, we are asking community members to think about this research and let us know what you think about the FASTEST study.

We would greatly appreciate you filling out a confidential survey by going to our website.