An emergency care research study of bleeding in the brain is to be performed in this area.

The <<FASTEST site>> is joining researchers at more than 100 other hospitals across the United States and other countries to conduct a research study of bleeding in the brain called FASTEST. This research study may affect you or someone you know. FASTEST is a research study involving patients who have had bleeding in the brain, also called intracerebral hemorrhage (ICH). ICH occurs when a weakened blood vessel in the brain breaks and bleeding accumulates in the brain. Most of this bleeding occurs within a few hours of onset of symptoms. The brain injury from ICH is usually very severe, over 40% of people with ICH die within a month, and only 20% can independently care for themselves after 6 months. There is currently no treatment for ICH that is scientifically proven to improve outcome. 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). One group receives rFVIIa intravenously over 2 minutes within two hours of onset of symptoms and the other group receives placebo. 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. Some patients will be enrolled without consent if a family member or representative is not rapidly available. Before the research study starts, we will consult with the community. We welcome your feedback and questions. For more information or to decline participation in this research study, please visit #####@.org or contact our research study staff at

(xxx) xxx-xxxx.

Primary Investigator: Dr. <name>, MD

Study Coordinator: <name>





An emergency care research study of bleeding in the brain.

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