



Information about a Research Study to:

**Prevent Repeat Strokes
in Patients with a Recent
Stroke of Uncertain
Cause
("cryptogenic stroke")**

The NAVIGATE ESUS research study is seeking a safe and more effective alternative to aspirin treatment to prevent another stroke in patients who already suffered a stroke of uncertain cause. "ESUS" stands for Embolic Stroke of Undetermined Source. Embolism describes a clot that forms in one part of the arterial system that is pumped into the brain to block a smaller artery and causes a stroke.

If you have suffered a stroke of this type, we would be pleased to consider you for participation.

WHAT IS THE STUDY TESTING?

Aspirin or other medications that inhibit blood platelets from sticking together to start clot formation is the current standard for preventing recurrent strokes in patients with ESUS.

Rivaroxaban is an anti-clotting medication called an anticoagulant. Rivaroxaban slows clotting by a mechanism that is different from aspirin. Since rivaroxaban was introduced in 2008, it has been given to over 12 million patients around the world.

Rivaroxaban is a more powerful anticlotting medication than aspirin and might prevent strokes better, but it also might cause more bleeding than aspirin. This research study will determine whether rivaroxaban should be recommended to prevent stroke instead of aspirin, considering both strokes and bleeding.

The NAVIGATE ESUS study is being done at 480 stroke research centers in 31 countries and will

involve 7000 people. It is sponsored by Bayer Healthcare, the maker of rivaroxaban.

If you decide to participate in this study, you will be asked to:

1. Take one pill every day from each of the two bottles of study medicines.
2. Come to the clinic every 6 months after the initial 1 month visit.
3. Agree not to take any aspirin or other anticlotting medications for the duration of the study, without checking with your NAVIGATE ESUS doctor.

You will not know which medication to which you have been assigned until the end of the study (either rivaroxaban or aspirin). We will not interfere with any other medication you are taking (e.g. diabetes medication), and you will remain under the care of your primary physician.

If you wish to learn more about this important project, please contact

us. We will be happy to answer your questions and to contact your primary doctor. We hope to learn the best preventive treatment for hundreds of thousands of patients with ESUS.

WHO IS ELIGIBLE TO PARTICIPATE?

- Patients with a stroke within the last 6 months
- Whose stroke was due to lack of blood flow to part of the brain
- Who do not have a heart rhythm disturbance called atrial fibrillation

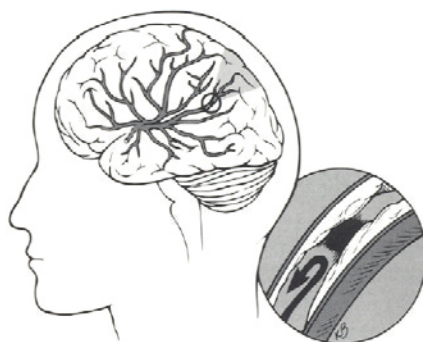
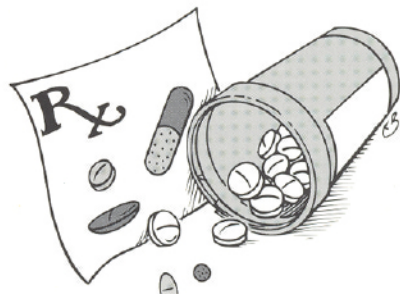
There are several other criteria that we can review if you are interested in participating.

Strokes are caused by blood vessel problems within the brain. Blood clots are involved in most strokes, and anti-clotting medications are used to prevent recurrent strokes.

NAVIGATE ESUS RESEARCH STUDY

Participants will be assigned by chance (called “randomization”) to receive either rivaroxaban (an anticoagulant medication) or aspirin (an anti-platelet medication). Treatment will continue for 1 to 3 years, and each person will be seen every 6 months in the research clinic.

You can help us to better understand how to prevent strokes. Participation is voluntary and your medical care will not be compromised should you decide not to participate. If you are interested in being part of this important clinical research study or would like more information, please contact a member of the study team listed in this leaflet. Thank you.



Site #:

Research Coordinator:

Institution:

Telephone #:
