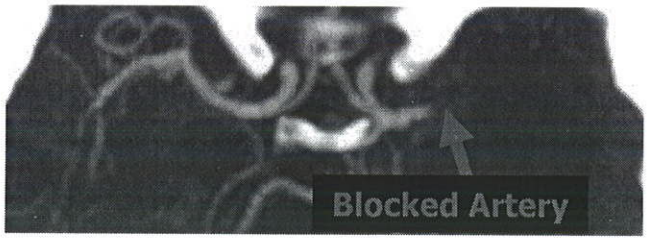
# Information Sheet (ARTSS-2)

**SUNY Downstate Medical Center**
**Department of Neurology**
**University Hospital Brooklyn**
**Kings County Hospital Center**

## *TITLE OF STUDY*
## *ARTSS-2: A Pilot, Phase IIb, Randomized, Multi-center Trial of Argatroban in Combination with Recombinant Tissue Plasminogen Activator for Acute Stroke*

We are asking if you want to be in a research study. This study is for individuals diagnosed with acute ischemic stroke ("brain attack"). These are caused by a blocked artery in the brain.




### Why is this research being done?
Recombinant tissue plasminogen activator (rt-PA) is given as standard-of-care treatment for strokes, but only reopens the blocked artery 20% of the time. Argatroban is a blood thinner that is FDA-approved and has been used for over 10 years. The purpose of this study is to see if there are any differences in treatment benefit at 3 months and treatment efficacy (ability to reopen the blocked artery) among patients who receive rt-PA and are randomized by computer to either low-dose Argatroban, high-dose Argatroban, or neither.

### *Who is doing the study?*
Dr. Steven Levine, Vice-Chair of the Department of Neurology, is in charge of this study at SUNY Downstate and Kings County Hospital Center. About 10 people will be enrolled in the study from these locations. About 105 people will be enrolled worldwide.

### *You cannot be in this study if you:*
- You are not at least 18 years old.
- You are pregnant.
- You have a history of bleeding in the brain, known blood vessel defect, or untreated brain aneurysms.

- You have had a significant bleeding episode [e.g. gastrointestinal (GI) or urinary tract] in the last 3 weeks.
- You have had a major surgery or serious trauma in the last 2 weeks.
- You have had a stroke or heart attack in the last 3 months.
- You have a history of liver problems or liver disease – including a current history of alcohol abuse (Your response will be recorded in the study record, and, in the case of a judicial summons, this information may be released to the authorities).
- You have had a brain tumor.
- You have participated in a drug or device study in the last 30 days.
- You are allergic to Argatroban or its agents.
- If you arrive at the hospital between 3 – 4.5 hours after your symptoms began, you cannot be in this study if:
    - You are greater than 80 years old
    - You are taking blood thinners
    - You have a history of stroke and diabetes.

### *What will happen to you if you decide to be in this study?*

Depending on the group, you will receive rt-PA and either low-dose, high-dose Argatroban by IV, or no Argatroban. Additional CT scans would be taken to look for bleeding and to see if the artery has opened. Additional blood draws will be needed to see how thin the blood may have become, and if adjustments are needed to the treatment dose. This will occur in the first 48 hours. Follow-up will occur at 7 days after treatment or at discharge (whichever comes first) and at 3 months after treatment.

### *What are the possible risks or benefits of being in the study?*

Argatroban and rt-PA can increase the risk of bleeding, though in a previous study involving 65 patients, low-dose Argatroban in combination with rt-PA was shown to be safe. Some patients who undergo CT-A may have an allergic reaction to the dye, which can be mild (rash) or more serious (very low blood pressure). While no benefits can be promised, it is possible that patients on Argatroban in combination with rt-PA may experience better recovery.

### *What are your other choices?*

The alternative to being in this study is to not participate. Your participation is voluntary. You don't have to be in this research study. You can agree to be in the study now and change your mind later.

### *If you have any questions or problems, whom can you call?*

If you have any questions about this study, you can page Dr. Steven Levine at (917) 252-0462 or call him at (718) 270-6362.