SHORT TITLE: VOYAGER

RESEARCH PROTOCOL TITLE: Vascular Outcomes studY of Asa alonG with rivaroxaban in Endvascular or surgical limb Revasculaization for peripheral artey disease (PAD)

PRINCIPAL INVESTIGATOR: Victor Weiss, MD

RESEARCH SPONSOR: Bayer HealthCare

STUDY PURPOSE
The purpose of this study is to find out about the safety and efficacy of rivaroxaban combined with aspirin in reducing the risk of major cardiovascular events (e.g., stroke or heart attack) after a person with vessel disease in their legs has had a revascularization procedure to improve blood flow. The FDA has not approved rivaroxaban for this use. The FDA has approved rivaroxaban for reducing the risk of clots in other conditions.

SUMMARY OF STUDY PROCEDURES
The number of study visits during this trial may vary depending on when the subject starts this study. Most subjects will complete a total of 8 visits over a period of 2 1/2 years (two and a half) Years. The anticipated duration of the study is approximately 2.5 years but could be extended depending on enrollment to approximately 4 years. During the study visits Subjects may have to give a blood sample, have the blood flow in your legs checked and answer a questionnaire.

ELIGIBILITY CRITERIA FOR SUBJECTS
Age 50 years or greater
Have documented lower leg occlusive disease

SUBJECT PAYMENT
Subjects will be compensated $50 (fifty) for each completed study visit.

RESEARCH LOCATION AND CONTACT PERSON
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