

SHORT TITLE: BEST-CLI

RESEARCH PROTOCOL TITLE: Randomized, Multicenter, Controlled Trial to Compare Best Endovascular versus Best Surgical Therapy in Patients with Critical Limb Ischemia

PRINCIPAL INVESTIGATOR: Victor J. Weiss, MD

RESEARCH SPONSOR: National Lung and Blood Institute of Health & Duke University

Clinical Trials.Gov Listing at:

<https://clinicaltrials.gov/ct2/show/NCT02060630?term=best+cli&rank=1>

STUDY PURPOSE

This study will compare the effectiveness of best available surgical treatment with best available endovascular treatment in adults with critical limb ischemia (CLI) who are eligible for both treatment options.

STUDY PROCEDURES

Subjects will be randomized to receive either open surgical treatment or endovascular treatment. There will be up to 10 visits for at least 2 years and up to 4 years and 2 months during which routine vascular testing will be done.

ELIGIBILITY CRITERIA FOR SUBJECTS

- Male or female, age 35 years or older.
- Critical Limb Ischemia, defined as circulation insufficiency with gangrene, non-healing ulcer, or rest pain.
- Candidate for both endovascular and open infrainguinal revascularization as judged by the treating investigators.
- Willingness to comply with protocol, attend follow-up appointments, complete all study assessments, and provide written informed consent.

SUBJECT PAYMENT

There is no compensation for participating in the study.

RESEARCH LOCATION AND CONTACT PERSON

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