New investigational treatments must be carefully tested through clinical research studies before pharmaceutical companies are allowed to sell them to the public. If a study demonstrates a treatment’s safety and effectiveness, the pharmaceutical company can then apply for approval to market its treatment to the public.

Clinical research studies are necessary to test and, ultimately, develop potential treatments for a wide variety of medical conditions. Volunteering in this study may help researchers to develop treatments to help others in the future. However, participation is completely voluntary, and a volunteer may leave the study at any time, for any reason.

What can you tell me about clinical research studies in general?

To learn more, please contact:
Stony Brook Surgery
(631) 444-5454

Visit www.REVIVECLI.com
or scan the code below with your smartphone:
I Have Critical Limb Ischemia (CLI): What does that really mean for my health?

Critical Limb Ischemia is a serious and life-threatening condition with more than 1 in 5 patients dying in the first year of diagnosis and nearly half of all CLI patients needing surgery to preserve their limbs.1, 2

CLI is a serious condition with few treatment options. Do I really have no other options?

It can be very discouraging when you have no more options for the treatment of your CLI. However, local doctors are now conducting studies to measure the effectiveness of a investigational product of CLI in patients with no options.

Tell me more about this study?

The purpose of the studies will be to evaluate the safety and effectiveness of injecting ixmyelocel-T into the affected leg of a patient with CLI.

Ixmyelocel-T is an experimental product that contains the patient’s cells. Ixmyelocel-T is created with patient’s cells from their bone marrow. A bone marrow collection will be performed as part of this study. A bone marrow collection is done by placing a thin needle in your bone (upper part of hip) and removing bone marrow through a syringe.

What would my participation in this study involve?

If you decide to be in this study, your participation will last about a year and a half. After a screening period of a month, the study doctor will decide if you are eligible. You will then return for your scheduled injections 14 days after your bone marrow has been collected. You will receive 20 injections of either ixmyelocel-T or a placebo, a substance that looks like an active injection but has no active ingredient, in the affected leg on that day.

You will have a 1 in 2 chance of receiving the injection containing ixmyelocel-T or the placebo. Neither you nor the study doctor will know if which one you received. However for medical reasons, your doctor may be given access to your information in case of emergency.

For the remainder of the study, you will be asked to come to the study center about 7 times. These visits include, but are not limited to, study-related physical examinations, vital sign measurements (temperature, heart rate and blood pressure), wound assessment and care, review of the current medications you are taking, and the collection of blood and urine samples.

What if I have more questions?

If you have any questions about ixmyelocel-T or about the study in general, please contact the study staff.

Who can participate?

Eligible participants must meet the following requirements:

- 35-90 years of age
- CLI diagnosis with tissue loss
- No reasonable standard-of-care options for surgery or revascularization
- A confirmed “no options” diagnosis by vascular specialist at the site
- Controlled on medical therapy indicated for CLI including antiplatelet therapy (such as daily aspirin) and statin or other cholesterol lowering therapy
- Have not had an amputation at or above the ankle on the affected leg
- Meets body mass index requirement (BMI)

Eligible participants will receive study-related medical procedures and evaluations at no cost. Reimbursement for time and travel may also be provided.

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