TRIAL PURPOSE

Sponsored by Biomet® Biologics, LLC, the MOBILE Study is evaluating an investigational treatment for critical limb ischemia (CLI) caused by peripheral artery disease (PAD). The treatment utilizes a device called the MarrowStim™ PAD Kit. It is designed to use a patient's own stem cells (immediately following the extraction of bone marrow) in an attempt to help restore blood flow and renew circulation to the affected leg and foot. The trial has been carefully designed and may provide an alternative treatment option for patients with CLI.

TRIAL DESIGN

The MOBILE Study randomizes patients to receive either MarrowStim™ treatment or a placebo (false treatment). Three out of every four patients will be selected for the MarrowStim™ PAD Kit treatment group. The procedure will take about one to two hours.

For those in the investigational MarrowStim™ treatment group, the procedure is as follows:

1. Harvest bone marrow from hip under general anesthesia
2. Load bone marrow into investigational device
3. Process bone marrow in investigational device
4. Deliver concentrated bone marrow to affected leg

Participation will require seven in-person follow-up visits after the initial procedure and seven follow-up phone calls over the course of the study or five years.

Are You a Candidate for The MOBILE Study?

ASK YOURSELF THESE QUESTIONS:

1. Do you have leg and foot pain that doesn’t go away, even at night?
2. Do you have sores on your legs or feet that won’t heal?
3. If you have been diagnosed with CLI, has your doctor told you that there are no other reasonable treatment options available to you that would preserve the limb?

If any of these statements apply to you, please contact your healthcare professional to learn more about PAD and CLI. To see if you qualify for the MOBILE Study, visit PADStudy.org and call 877-788-3972.

Talk to your doctor and visit PADStudy.org to learn more about the MOBILE Study.