

The MOBILE Study FAQ for Potential Subjects

1. What is the MOBILE Study?

The MOBILE Study is investigating a device called the MarrowStim™ PAD Kit for people like you who have critical limb ischemia (CLI), a condition where blood flow to the leg and foot is limited. The investigational treatment includes removal of the bone marrow from your hips, which is then processed in the investigational device to separate the stem cells for delivery by injection to multiple sites in your affected leg. The goal of the study is to restore blood flow and renew circulation to your leg and foot and evaluate the efficacy of the MarrowStim™ PAD Kit to prevent or delay major amputation and/or death.

2. What is the treatment process for the MOBILE Study?

The investigational treatment involves withdrawal of bone marrow from your hips and processes the bone marrow in the investigational device to separate the stem cells. The stem cells are then delivered via injections to multiple sites in the affected leg to restore blood flow and to renew circulation to your leg and foot. The MarrowStim™ PAD Kit treatment process takes about one to two hours. Three out of every four patients will receive the investigational treatment, while one out of four will receive a placebo (false) treatment. In-person follow-up visits are required at weeks 6, 12, 24, 36, and 52, and at years 2 and 3, following the original procedure. Phone call follow-up is required at weeks 3, 9, 18, 30, and 44, and at years 4 and 5, following the original procedure.

3. Where are the stem cells taken from? Are they embryonic?

No, the stem cells are not embryonic, but taken from your own bone marrow in your hips.

4. How will I know if the treatment is working or not?

The study is designed in a way that doesn't allow you to know if you're receiving a placebo or the experimental treatment. Once the trial period is over, the physician will be able to tell you if you received the treatment or placebo, and if the treatment worked for you.

5. What is the chance I will receive a placebo?

There is a one in four chance you will receive placebo, however if you are placed in the placebo group you may have an opportunity following the trial to receive the investigational treatment if you continue to meet certain criteria for entry in the study.

6. What are the risks involved with participating in the MOBILE Study?

Potential risks associated with participating in the MOBILE Study may include minimal discomfort or bruising from drawing blood, anemia (low red blood cell count), minor complications from bone marrow extraction, hip soreness following treatment, flu-like symptoms for the first several days after the procedure, tenderness of the calf or leg, potential blood clots in veins, allergic reactions to the treatment, and infection. The trial is registered with the FDA and patients are carefully monitored for adverse (negative) effects and treated accordingly throughout the duration of the study.



7. How long will the MOBILE Study take?

The study will take one year to complete from the time of your initial procedure. Follow-up will be required until five years following the original procedure.

8. Where are the study sites?

The clinical trial sites include some of the most highly-respected medical institutions in the country, experienced in treating this condition. Visit PADStudy.org to identify a clinical trial site near you.

9. What would make me a candidate for the MOBILE Study?

First review these three questions as a pre-screening for your eligibility:

- 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.

10. How do I register for the MOBILE Study?

Visit PADStudy.org to identify a clinical trial site and study coordinator near you. Once you have identified a clinical trial site you can contact the site coordinator directly to begin the screening process.

11. Am I enrolled automatically once I contact the clinical trial site?

No, once you contact the clinical trial site you will have to undergo a thorough screening process to confirm if you qualify for the trial. If you qualify, you will be asked to begin the year-long commitment in the trial.

12. How often do I need to come to the study site?

You will be required to visit the clinical trial site a minimum of six times, including the treatment visit, over the course of the year. After the first year, you will be required to visit the site for two follow-up office visits. The first will take place two years following the original procedure and the second will take place three years following the original procedure. Additional phone call follow-up will be required at years four and five following the original procedure.

13. Do I need health insurance to participate in this trial?

In many cases, you do not need health insurance to participate in this trial. If you qualify and are enrolled in the clinical trial, the sponsor will cover all medical costs associated with the study including the pre-screening, the procedure and post-procedure follow up.



14. Will I be reimbursed for my participation in the MOBILE Study and any travel costs to get to the trial site?

If you enroll in the MOBILE Study, you may be reimbursed for your time and travel costs up to \$200 per completed visit for a total of \$1,800.

15. What is an informed consent form? Who can address my questions about it, if I have any?

The informed consent is a form you must sign before enrolling in the clinical trial. Prior to enrollment, a healthcare professional from the study site, likely the study investigator or study coordinator, will review the form with you and outline the clinical trial process and your role in it, the likelihood that you'll receive the investigational treatment or a placebo, and all risks associated with participating in the trial. If you have any questions you can call 877-788-3972.

16. Can I leave the MOBILE Study at any time?

You should not enroll in the trial unless you are willing and able to honor the time commitment of the trial of a minimum of six in-person office visits, including the treatment visit, and five follow-up phone calls over the course of the year. However, you are free to leave the study at any time.

17. How will my progress be monitored once the MOBILE Study is complete?

During the MOBILE Study you will remain under your primary physician's care for all medical conditions not related to CLI. Following the trial, we ask you to continue to see your primary physician to monitor all your health related questions and concerns, as they arise. If you are placed in the placebo group, you will have an opportunity to receive the investigational treatment if you continue to meet certain criteria for entry in the study.

18. Will results of the MOBILE Study be provided to me?

Not immediately. Once the study is complete, it will take time for the study sponsors at Biomet® Biologics, LLC to compile the results. When the results are complete, they are typically published for public knowledge.

