The PACE Study Key Points for healthcare professionals

Study Design and Purpose

This study is a randomized, double-blind, placebo-controlled, multicenter trial that will evaluate the physiologic effect, safety and efficacy of autologous bone marrow-derived aldehyde dehydrogenase bright (ALDHbr) cells in patients with peripheral artery disease (PAD) and intermittent claudication, to determine if the ALDHbr cells increase peak walking time by increasing blood flow in the affected limb.

The PACE study randomizes subjects in a 1:1 ratio to receive either ALDHbr cells or placebo, by intramuscular injection into the affected leg. Commitment to the study involves eight study visits over a six month period and a phone call at twelve months. Study participants continue to be followed by their routine care providers during study participation.

Primary and Secondary Endpoints

Primary endpoints are peak walking time and changes in perfusion as measured by MR imaging. The primary endpoints will evaluate change from baseline to six months between the two study groups.

Secondary endpoints include change over time of: pre and post-exercise ABI, claudication onset time, peak walking time at three months and patient perception of walking impairment as well as other peripheral artery disease symptoms.

To Qualify for PACE

Patients must be over the age of 40 with intermittent claudication and ABI <.90. Qualified candidates will carry a confirmed diagnosis of PAD and have >50% stenosis of at least one artery among the superficial femoral, popliteal and/or infrapopliteal arteries. This stenosis may be determined by Duplex ultrasound, lower extremity CTA, lower extremity MRA, or lower extremity catheter-based contrast arteriography.

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Study treatment procedure

All subjects undergo bone marrow harvest. This is an outpatient procedure, and is performed in a hospital operating room setting with the use of conscious sedation. The bone marrow is transported to a facility in Houston, Texas for processing. Approximately two days after the bone marrow harvest, the subject returns for injections of either placebo or ALDHbr cells. A total of ten intramuscular injections are delivered into the more symptomatic lower limb. Study procedures are provided at no cost to the subject and a study stipend is available to assist with travel expenses.

Study Sponsor

The PACE study is being conducted through the Cardiovascular Cell Therapy Research Network (CCTRN), and is sponsored by the National Heart Lung Blood Institute (NHLBI) of the National Institutes of Health (NIH).

Study Sites

Study sites include locations in Indiana, Kentucky, Florida, Minnesota, Texas and California. Contact us to learn more.

This study is conducted by researchers in the Indiana University School of Medicine. For more information or to determine qualification for the study, contact us at **cvtrials@iupui.edu** or **855.333.3260.**

To learn more about the Indiana Center for Vascular Biology and Medicine at the IU School of Medicine, visit **http://vascularbiomed.medicine.iu.edu**

THE STRENGTH IT TAKES

Indiana University Health

This information is intended for professionals only