

Stem Cell Mediated Angiogenesis Study”

The “Stem Cell Mediated Angiogenesis Study” is an FDA and IRB approved Phase I clinical trial to examine how safe and effective adult stem cells are for stimulating the development of new vessels in the legs of patients with severe peripheral vascular disease. The stem cells are obtained from the patient's own bone marrow (autologous) and the special type of cell that is used, the vascular progenitor cell is then separated from the bone marrow and injected directly into the muscle of the calf of the diseased leg. The procedure presently requires a bone marrow harvest from the hip bone on the back and a general anesthetic. The injection of the vascular progenitor cells is done with sedation. The process is done in two stages. The first stage is harvesting the bone marrow, which requires about an hour. While the patient recovers from the anesthesia the bone marrow is prepared, which requires about 3 hours, and then the cells are injected into the leg, which requires about 30 minutes. Presently the patient is admitted overnight.

Eligible patients are those with severe peripheral vascular disease causing pain in the foot or leg at rest or an ulcer no larger than 1 inch wide. Patients also must be over 18 years of age, able to give consent for procedures, and have normal kidney function. Having diabetes is acceptable providing that it is well controlled (hemoglobin A1c less than 6.5 %). Patients that cannot participate in this study are those with heart failure or a history of cancer. Eligible patients will have to undergo a series of screening studies to make sure that they do not have an undetected cancer (includes mammography and PAP smear for women, measuring prostatic specific antigen for men, and checking stool samples for blood in both men and women). After the screening tests enrolled patients will have an arteriogram, blood pressure recordings in the leg, measurement of oxygen levels in the skin, and a magnetic resonance imaging study to look at the muscle and arteries of the diseased leg. The study is 12 weeks long and will require travel to and from Indiana University Medical Center at 2 weeks, 4 weeks, 8 weeks and 12 weeks after being treated.





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