TGAIT Study Key Points for healthcare professionals

Study Design and Purpose

The *TGAIT* Study is evaluating an investigational treatment for critical limb ischemia (CLI) caused by peripheral artery disease (PAD). The treatment involves a device called the Icellator Cell Isolation SystemTM which processes a patient's own adipose tissue (harvested from a minimally invasive liposuction of around 100 cc) to obtain a preparation rich in adipose-derived stem and progenitor cells that can be used in an attempt to restore blood flow and rescue the affected leg and foot from ischemia. The stem/progenitor cell preparation is available from the fat within less than 80 minutes, and is used at the point of care.

The protocol takes about three hours. After the procedure there are five in-person follow-up visits and one follow-up telephone call during the course of approximately six months. Study procedures are provided at no cost to the subject.

Primary Endpoints

Time to treatment failure, with "treatment failure" defined as the composite of major amputation of the study limb or all cause death (Amputation Free Survival). The primary endpoint for initial safety is adverse events considered potentially related to the study treatment through 26 weeks post-procedure.

To Qualify for TGAIT

- Critical limb ischemia (CLI), defined as rest pain (Rutherford Category 4), or minor tissue loss of the limb (Rutherford Category 5), and with either:
  - ABI ≤ 0.5 or ankle artery occlusion pressure ≤ 60 mm Hg, or
  - TBI ≤ 0.5 or toe artery occlusive pressure < 50 mmHg, or
- No reasonable open/endovascular surgical options

continued

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- No current malignancy or history of previous malignancy within the last five years, with the exception of adequately treated non-melanoma cutaneous carcinoma (basal cell or squamous cell carcinoma of the skin)
- Prior to enrollment, subjects meeting the sex/age criteria below must undergo cancer screening and have corresponding evidence of the following:
    i) if > 50 years of age (male or female), a colonoscopy or fecal occult blood test negative for cancer, performed within the last year
    ii) for males > 45 years of age, a prostate specific antigen (PSA) test negative for cancer, performed within the last two years
    iii) for females > 40 years of age, a mammogram negative for cancer, performed within the last two years
    iv) for females of any age, a Papanicolaou (pap) smear negative for cancer, performed within the last two years
- Age 21 years or greater and competent to give consent
- Females of child bearing potential agree to use acceptable methods of contraception for the duration of the trial. Sexually active males agree to use an accepted and effective method of contraception for the duration of the trial

Study Sponsor

The TGAIT study is being conducted through Tissue Genesis, Inc., with a funding sponsor of US Army Medical Research and Materiel Command, Telemedicine & Advanced Technology Research Center.

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**

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Indiana University Health

This information is intended for professionals only