

Bioelectric Stimulation + Amniotic Fluid in Diabetic Foot and Leg Ulceration

Purpose

The investigators hypothesis that use of a bioelectric stimulator device, that recruits stem cells via a homing signal and increases blood flow to the leg and foot, will speed up ulcer healing in symptomatic diabetes when used in combination with amniotic fluid membrane applications on the wounds.

Condition	Intervention
All Subjects Will Receive Best Medical Therapy. Those Randomised to Device Will Additionally Use the Device	• Device: VascuStim bioelectric stimulator device • Biologic: Amniotic fluid membrane • Other: Best Medical Therapy

Study Type: Interventional

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: Bioelectric Stimulation + Amniotic Fluid in Diabetic Foot and Leg Ulceration

Resource links provided by NLM:

[MedlinePlus](#) related topics: [Diabetic Foot Foot Health](#)

U.S. FDA Resources

Further study details as provided by VascuStim a Leonhardt Ventures Co.

Primary Outcome Measures:

Ulcer healing [Time Frame: 16 weeks] Time to 50% healing of leg ulcer, as measured by volume (3D camera)

Secondary Outcome Measures:

Quality of life [Time Frame: 16 weeks] Improvement in quality of life questionnaire values, comparing baseline to 6 weeks with treatment

Target Enrollment: 300 to 1200 patients

Expected Study Start Date: October 2017

Expected Study Completion Date: December 2018

Primary Completion Date: December 2018 (Final data collection date for primary outcome)

measure)

Arms and Assigned Interventions

Arms	Assigned Interventions
Active Comparator: No device Treated with best medical therapy	Other: Best Medical Therapy Seen in outpatient clinic for wound care and ongoing advice
Experimental: Device + Biologic As well as receiving best medical therapy, these people will be given the VascuStim device therapy via stimulation electrodes applied on their affected leg. They will be stimulated for 2 hours every three days during a 16 week course of treatment. Amniotic fluid membranes will be placed on all wounds with renewed application every ? days.	Device: VascuStim bioelectric stimulator device Placed on the lateral aspect of the knee, when activated it causes the leg to twitch + amniotic fluid membrane placed on wounds Other: Best Medical Therapy Seen in outpatient clinic for wound care and ongoing advice

Detailed Description

Diabetes affects approximately 347 million people worldwide, and by 2030 the WHO projects that diabetes will be the 7th leading cause of death. Diabetic foot ulcers are estimated to occur in 15% of all patients with diabetes, often co-existing with neuropathy and peripheral vascular disease which compromise the limb's ability to heal. Foot infections in this cohort are common, and diabetic foot ulcers serve as a portal for infective organisms to enter the body. Unchecked, infection can spread contiguously to involve underlying tissues, including bone. A diabetic foot infection is often the pivotal event leading to gangrene and lower extremity amputation.

Diabetes accounts for over one million leg amputations every year, and represents 60% of all amputations in developed countries.

Due to the potential for rapid progression of infection, and the gravity of potential complications, diabetic foot problems are handled aggressively in the community, with a low threshold for referral to secondary care. Out-patient clinics involve a multidisciplinary team of clinicians, podiatrists and vascular surgeons. Good foot care is taught to all diabetic patients, and

treatment with antibiotics, debridement and revascularisation should occur as a matter of urgency where appropriate.

The device to be tested increases blood flow to the limb via controlled specific bioelectric signals in sequence for controlled expression of key specific angiogenesis promoting proteins such as VEGF, eNOS, PDGF, HIF 1 alpha, HGF, EGF, IGF-1 and Tropoelastin. The VascuStim bioelectric stimulator also has controlled signals for recruiting resident autologous stem cells from the patient's own bone marrow, fat and circulating blood with a homing signal (SDF-1 + PDGF) and controlling proliferation of those recruited cells and their differentiation. It is hypothesized that increasing blood flow and regenerative stem cells to the limb, much as surgical revascularisation, will aid the legs ability to heal and fight infection. After training, it can be used by patients on themselves and is suitable for out-patient therapy.

The sponsor of this study has previously completed limb salvage and diabetic foot ulcer pre-clinical and pilot proof of concept clinical studies in collaboration with collaborating investigators with electrical stimulation with successful results. Separately they have sponsored limb salvage studies with the injection of adipose derived cells with successful results.

What is unique about this study is the combination of controlled expression of regenerative and angiogenic proteins via bioelectric stimulation and the application of amniotic fluid membranes on the wounds.

A number of investigators have reported accelerated healing of wounds with the application of amniotic fluid membranes.

The investigators wish to evaluate both the short- and longer-term effects of a bioelectric controlled protein expression stimulator combined with amniotic fluid membranes on diabetic foot ulceration wounds as a therapeutic intervention.

Eligibility

- **Ages Eligible for Study:** 18 Years and older (Adult, Senior)
- **Sexes Eligible for Study:** All
- **Accepts Healthy Volunteers:** No

Criteria

Inclusion criteria

- 18+ years old
- Type 2 diabetes on best medical therapy
- Active foot ulceration, present <3 months

Exclusion criteria

- Pregnancy
- Pacemaker
- Metal implants in the legs (below knee)

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier:

Sponsors and Collaborators

VascuStim a Leonhardt Ventures Co.

Investigators

Principal Investigator:

More Information

Responsible Party: VascuStim a Leonhardt Ventures Co.

ClinicalTrials.gov Identifier:

Other Study ID Numbers:

Study First Received:

Last Updated:

Additional relevant MeSH terms:

Diabetic Foot, Foot Ulcer, Diabetic Angiopathies, Leg Ulcer, Skin Ulcer, Diabetic Neuropathies, Vascular Diseases, Cardiovascular Diseases, Skin Diseases, Diabetes Complications, Diabetes Mellitus, Endocrine System Diseases, Foot Diseases