A Randomized, Controlled Study, Assessing The Safety And Efficacy Of The MicroVas® Device In The Treatment Of Patients With Diabetic Peripheral Neuropathy In The Lower Extremities

IRB #: Pro00001496

*** A Preliminary Outcome Report ***

Conducted At The University Of Texas Health & Science Center, And the Texas Diabetes Institute San Antonio, Texas

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Information About The Research

This clinical trial was conducted at the University Center For Community Health/Texas Diabetes Institute, San Antonio, Texas, to determine the safety & efficacy of the MicroVas device in the treatment of diabetic peripheral neuropathy in the lower extremities. The MicroVas device is considered to be durable medical equipment, has received FDA 510-K clearance, and is a patented, non-invasive vascular treatment device. It incorporates a faradic magnetic waveform, delivered by electrodes transcutaneously, to obtain full muscle fiber penetration in order to achieve deep muscle stimulation, lymphatic stimulation, and restore calf pump mechanical function, which causes blood to pump more efficiently and increase blood perfusion to the lower extremities to ultimately rejuvenate nerve function which had been damaged by the diabetic peripheral neuropathy. The MicroVas device is exclusively marketed worldwide by neuroVasix, inc., the sponsor of the clinical trial.

MicroVas Trial Investigators

Dr. Lawrence Harkless, D.P.M. – Principle Investigator
Dr. Javier LaFontaine, D.P.M. – Principle Investigator
Dr. Hiro Shibuya, D.P.M. – Investigator
Rick Hess, M.S. – Clinical Trial Coordinator
Referring Physicians: Dr. Rosemary Michelle, D.P.M., Dr. Steven Krych, D.P.M., Dr. Michael Van Pelt, D.P.M., Dr. Karen Brooks, D.P.M., Dr. Lawrence Harkless, D.P.M., Dr. Javier LaFontaine, D.P.M., Dr. Hiro Shibuya, D.P.M.

Clinical Trial Protocol

Rick Hess, M.S., clinical trial coordinator, and Dr. Javier LaFontaine, D.P.M., clinical trial principle investigator wrote the protocol for the study, which was I.R.B. approved by The University Of Texas Health And Science Center, San Antonio, Texas I.R.B. board panel.

The protocol dictated a patient sample size of twenty-four (24) patients to enroll with an expected twenty (20) patients to complete. An approved randomization program was used to make twelve (12) patients receive the actual MicroVas treatment, or the TX group, and twelve (12) patients receive the MicroVas placebo, or "sham" device, being the control, or SH group. The trial was to run with each patient in the TX group and each patient in the SH group to receive thirty-six (36) clinic visits. These clinic visits were protocol requested to occur three (3) times per week with the treatment duration, or application of the MicroVas TX or SH device being forty-five (45) minutes per session. Inclusion factors for enrollees were male or female out-patients, older than eighteen (18) years and younger than ninety-nine (99) years, diagnosis of diabetic peripheral neuropathy by referring physician, daily leg pain and/or numbness > six (6) months, evidence of adequate blood perfusion to extremities, history of compliance and must have been able to sign and give informed consent prior to any study activities. Exclusion factors were unable to consent for them selves, patients with active charcot, have gangrene or severe vascular compromise which may necessitate bypass or amputation, untreated infection or cellulites, untreated osteomylitis, collagen vascular disease, presence of malignancy in extremities, uncontrolled hyperglycemia, cancer or AIDS and history of severe liver disease.

Study Methodology And Procedures

Clinical assessments included nerve conductivity testing using the "Brevio" nerve conductivity device done at baseline and at one month post trial follow up, TcPO2 done at dorsum of foot at baseline, week six (6) and at post trial follow-up using the Radiometer TcPO2 device, digital photos at baseline and post trial follow-up, laser Doppler at baseline and one (1) time per week, vibration sensory threshold testing at baseline, visit eighteen (18) and at post trial follow-up, Semmes-Weinstein monofilament testing at baseline, visit eighteen (18), visit thirty-six (36), and one month post trial follow-up. Questionnaires for pain, impairment score and quality of life data included McGill Pain Questionnaire-Short Form (SF-MPG) done prior to each treatment, SF-36V2 done at baseline, week three (3), six (6), twelve (12) and one month post trial follow-up, brief pain inventory- Short Form 1093 done baseline and each treatment and one (1) month post trial follow-up, neuropathy impairment score done at baseline, week six (6) and week twelve (12) and one (1) month post trial follow-up, and visual analog scale done at baseline, before each treatment, and one (1) month post trial follow-up.

All patients were screened and questioned at time of physician referral for inclusion/exclusion parameters and compliance risk by the clinical trial coordinator prior to patient receiving informed consent form. History and physical was performed on each patient after receipt of informed consent and prior to first device application.

*Preliminary Outcomes To Date

The outcomes so far to date in the clinical trial assessing the efficacy & safety of the MicroVas device in the treatment of diabetic peripheral neuropathy in the lower extremities have shown to be quite remarkable.

Out of the patient sample size of twenty-four (24) patients, twenty (20) patients completed the thirty-six (36) visit cycle. The four patient dropouts were all control or SH patients who dropped out of the trial in the very early stages. There were ten (10) treatment, or TX patients who completed and ten (10) control, or SH patients who completed.

In the TX patient category all patients displayed marked clinical results in the objective clinical assessment category as well as the subjective questionnaire category. Two (2) of the TX patients which had been on disability prior to starting the trial, went back to work. One (1) of the TX patients was unable to ambulate without the use of a walking cane prior to starting the trial, and is now displaying normal ambulation without the need or use of the walking cane. All TX patients have shown marked improvement in quality of life, tremendous reduction in pain, and a dramatic increase in sensation in the lower extremities. All TX patients who have had post one (1) month trial follow-up to date have shown lasting residual effect of the MicroVas device treatment.

The patients enrolled in the control, or SH group, have shown no noticeable improvement, neither clinically objective nor subjectively by questionnaire.

It is in our opinion with results so far to date that the MicroVas device proves to be of utmost efficacy in the treatment of diabetic peripheral neuropathy in the lower extremities.