EPIFLO

Study Overview

Brief Summary:

The purpose of this clinical trial is to evaluate Transdermal Continuous Oxygen Therapy (TCOT) as an adjunct to surgical wound healing in subjects undergoing vascular surgery for lower extremity arterial occlusive disease. It is the intention of this study to administer oxygen using the TCOT approach to the surgical sites of subjects undergoing the surgery and to monitor the healing of the incision as well as infection rate. The hypothesis is that oxygen delivered transdermally to the surgical site in a continuous manner for up to 28 days will accelerate the healing process and reduce the infection rate compared to the Standard of Care.

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Detailed Description:

This Safety & Efficacy Study will be a randomized controlled trial of 100 subjects (Parallel design) aged 18 - 90 years who are scheduled to undergo vascular surgery at the University of Maryland Medical Center (UMMC) hospital. 50 subjects will be recruited for the control arm and 50 for the treatment arm. Subjects who meet the inclusion/exclusion criteria will be randomized to receive the treatment device with Standard of Care or Standard of Care alone (1:1). The most proximal (e.g., groin) incision (subject to safety exclusion) will be studied.

The expected study treatment duration is 4 weeks. This means the subjects will be seeing their physician weekly for the first 4 weeks following their surgery, once they are recruited for the study.

During the study, there will be five study treatment visits: Study visit 1 (day 0) is the day of the surgery and of randomization. For those randomized to the treatment arm of the study, the EPIFLO device will be applied on this day immediately following surgery. For those randomized to the control group, standard gauze dressing will be applied to their incision site. The second study visit is 7 days following surgery (day 7) and the third, fourth, and fifth study visits are on days 14, 21, and 28 respectively. On the third study visit (day 14), a new EPIFLO will be applied and the old one discarded for those in the treatment arm of the study, because FDA has cleared each EPIFLO-15 device only for a maximum of 15 days of use, after which the used device must be disposed (single use, single patient, disposable device). The 5th study visit (Day 28), will be the final treatment study visit for all subjects, regardless of which treatment group they are in.

Those subjects whose incisional wound has healed during the study treatment period (28 days) will come in for a healing confirmation visit two weeks after it's noted to be healed. Note that an incision is not declared healed until the healing is confirmed after a two-week period after the first observation of complete healing. They will then have one

final study visit, approximately 90 days from the first observation of wound closure, as their last study visit.

All subjects whose incisions have not completely healed by the fifth study visit (day 28) will also come in for one final study visit, approximately 90 days following their surgery, to have the study doctor assess the condition of the incision.

The investigational device of this protocol is the EPIFLO® Transdermal Continuous Oxygen Delivery. Components of this unit include: Small, silent disposable, battery-operated oxygen concentrator capable of delivering 98% to 100% oxygen (balance moisture) for fifteen days at a rate of ~3.0 ml/hour; and 36" long sterile cannula (tube) that conveys the oxygen from the concentrator device to the area beneath the bandage overlying the wound. EPIFLO is intended to provide transdermal, continuous oxygen delivery to chronic wounds. EPIFLO concentrates oxygen from atmospheric air and delivers the concentrated oxygen to the region of the wound bed creating an oxygen-enriched environment intended to promote the healing process in chronic wounds as an adjunct to standard wound care in wound management and treatment.

EPIFLO is worn in a convenient location in the body within 4-5 feet of the wound, beneath clothing without impairing its operation, and the subject is free to ambulate and continue with normal daily activities while being treated 24 hours per day for 15 days. The EPIFLO unit measures 2" x 2.5" x 1" and weighs 3.5 oz. A pouch (with belt loop) and arm band are provided to facilitate wearing of the device.

A Safety Monitor will be selected from unbiased wound care experts/vascular surgeons, selected by the Investigator and will not be affiliated with the sponsor of this study. The monitor charter will define the specific processes and procedures by which their assessments will be conducted.

All study data will be presented in subject data listings. Statistical analyses, if applicable, will be performed using SAS® for Windows, version 9.1 or later. Descriptive statistics (n, mean, standard deviation, median, minimum and maximum) will be calculated by treatment group for continuous variables. Frequencies and percentages will be presented by treatment group for categorical variables. Missing data will not be imputed.

The disposition of all subjects who sign an ICF will be provided. The numbers of subjects randomized, completed, and discontinued during the study, as well as the reasons for all post-randomization discontinuations will be summarized by treatment group, for all centers combined and each center separately. Disposition and reason for study discontinuation will also be provided as a by-subject listing.

Demographics and baseline characteristics, including physical examination and medical history will be summarized by treatment group for Intent to treat (ITT) and Safety populations.

Data will be summarized, descriptively, according to the variable type:

- Continuous data: summaries will include the number of observations, mean, standard deviation, median, and minimum and maximum values.
- Categorical data: frequePrimary endpoint The primary endpoint of closure of the surgical incision between the active and control populations will be tested using a repeated measures analysis, specifically using a mixed model for repeated measures. This will be tested with a necessary p-value of .05 or smaller to demonstrate significance regarding the interaction between treatment and time of the follow-up visit when the measurement was taken.

The test statistic will follow a t-distribution with n-2 degrees of freedom, where t=(Interaction between time and treatment)/(Standard Error of the interaction) is the test statistic for testing the significance of treatment on wound healing, where n is the total number of patients in the study with at least one measurement taken for % of wound healed.

The test for significance will be conducted using a t-test against the Null Hypothesis that the impact of the interaction between treatment and measurement period on wound healing is zero. The test for significance will be made at α=.05. The statistical analysis will be conducted in SAS using the MIXED procedure with the specifications of maximum-likelihood estimation methods, model repeated measures, blocking by patient, and unstructured covariance matrix.

Secondary endpoint The secondary endpoint regarding rate of infection between the EPIFLO treatment and the control treatment will be tested at a significance level of .05 using Barnard's test. A 2x2 contingency table will be made between patients in the Active and Control arms, as well as the patients' incidences of at least one surgical site infection. The statistical analysis will be conducted in SAS using the FREQ procedure with the specification of EXACT BARNARD.

Any correlation between the primary and secondary endpoints will be assessed first by calculating the correlation coefficients for the secondary end points. If the secondary endpoint was found to be correlated with primary, then further analysis will be done only if primary endpoint shows statistical significance as per the study success rule defined above. If the secondary endpoint is not correlated with primary, then, further analysis of the secondary endpoint will be carried out as described below. The secondary endpoint will only be tested if the primary endpoint is statistically significant by the study success rule defined above.

A multiplicity adjustment strategy (to be fully described in our Statistical Analysis Plan) would be followed to control the overall Type I error at 0.05 level.

The SAP will fully describe the procedure to control the overall type I error rate at 5% level (or below) using the methodology described in the literature (ICH E9 (1998) on "Statistical principles for clinical trials")

Supportive Analysis To assess the consistency of the Primary Analysis results, supportive analyses will be conducted using the Per Protocol (PP) population. Statistical methodology for the supportive analyses will be the same as that of the primary analysis, with the exception of the analysis population used. The PP population will be used for the supportive analysis while ITT population will be used for the primary analysis. Subjects with no post baseline value for the primary endpoint will be considered NOT HEALED in this analysis.

Safety Analyses The Safety population will be used for the analysis of safety endpoints. For continuous variables data will be summarized by treatment using n, mean, SD, minimum and maximum values. For categorical variables data will be summarized by treatment using frequency and percentage. No inferential statistics are planned.

ncy counts and percentages will be used.

All aspects of the study will be conducted according to the principles of Good Clinical Practice (GPD), the Declaration of Helsinki (1989), the provisions specified in Title 21 Parts 50, 54, 56, and 812 of the U.S. Code of Federal Regulations, this protocol, and all federal, State, and local laws of pertinent regulatory authorities.

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OFFICIAL TITLE

A Prospective, Randomized, Crossover Study of Transdermal, Continuous Oxygen Therapy for Surgical Site Wound Healing in High- Risk Subjects Undergoing Lower Extremity Revascularization

CONDITIONS

Surgical Wound Healing
Lower Extremity
Revascularization
Incision

INTERVENTION / TREATMENT

Device: EPIFLO

STUDY START (ACTUAL)

2019-03-07

PRIMARY COMPLETION (ESTIMATED)

2022-07-31

STUDY COMPLETION (ESTIMATED)

2022-07-31

ENROLLMENT (ESTIMATED)

100

STUDY TYPE

Interventional

PHASE

Not Applicable

OTHER STUDY ID NUMBERS

EPF-418

Resource links provided by the National Library of Medicine 

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

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