European Observational Study of the Sapheon* Closure System for the Definitive Treatment of Incompetent Great Saphenous Veins: A Prospective Single Arm Multicenter Clinical Observational Study

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5.1 Study ObjectivesThe primary objective for this clinical observational study is to assess the role of the Sapheon Closure System in closure of incompetent great saphenous veins in a routine clinical setting.5.2 Study HypothesisThis is an...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Venous varices
Study type	Observational non invasive

Summary

ID

NL-OMON37900

Source
ToetsingOnline

Brief title
eSCOPE Study

Condition

- Venous varices

Synonym
Venous Incompetence (valve leakage) of the great saphenous vein

Research involving

Human

Sponsors and support

Primary sponsor: Sapheon Inc.
Source(s) of monetary or material Support: sapheon inc

Intervention

Keyword: Glue Closure System, Incompetent great saphenous vein, Sapheon

Outcome measures

Primary outcome

This is an observational study on an approved device. Efficacy and safety (adverse events) will be compared with appropriate literature reports to determine if the results of the treatment of reflux disease with the Sapheon Closure System (SCS) Kit are consistent with or not inferior than the expectations of the medical community for alternative treatments, specifically Laser Thermal Ablation and Radiofrequency Ablation.

* The Primary endpoint is duplex ultrasound proven great saphenous vein closure with lack of pathological reflux at prescribed intervals.

Efficacy: The ability of the Sapheon Closure System (SCS) Kit to treat venous reflux by closing the great saphenous vein.

During the procedure, the primary measures are defined as follows:

* Procedural Success (complete closure) * vein closure along the entire treated vein segment due to the initial Sapheon Closure System directed administration of the Sapheon Closure Adhesive (SCA). No discrete segments of patency * 10cm.

* Procedural Failure * inability to attain vein closure during the procedure with discrete segments of patency > 10 cm.

At all follow-up, the primary efficacy measures are:

* Complete Closure * Duplex ultrasound proven vein closure along the entire treated vein segment due to the initial Sapheon Closure System directed administration of the Sapheon Closure Adhesive (SCA). No discrete segments of patency * 10cm.

* Recanalization/Patency * significant recanalization/patency in a treated vein that was previously closed or partially closed, or was an initial procedural failure and has discrete segments of >10cm of patency

Secondary outcome

7.2 Secondary Endpoints

* The Secondary endpoint is safety, reflected by the rate of occurrence of all adverse events (procedure and non-procedure related; serious and non-serious). Safety: Evaluation of safety will be accomplished by carefully monitoring and recording the incidence of adverse events during the procedure, immediately after the procedure, and during a 6-month follow-up period which includes follow-up visits 24-72 hours, and 1, 3, and 6 months post procedure.

7.3 Third Endpoint

Quality of life and pain

* Patient satisfaction and Quality of Life measured by EQ5D, AVVQ and Adverse reactions, at prescribed time periods pre- and post-procedure (see Table 1).

* Venous Clinical Severity Score at prescribed time periods pre- and post-procedure (see Table 1).

* Pain during the procedure, diary (VAS) on use of analgesics, at proscribed time periods pre- and post-procedure (see Table 1). Pain reported during the

first 30 days by patient diary VAS.

Study description

Background summary

Venous insufficiency of the lower extremities is a very common condition that is influenced by genetic and mechanical factors, and is a chronic and progressive disorder. The lower extremity venous system consists of the superficial system (e.g. great and small saphenous veins and saphenous tributaries) and the deep system (e.g. femoral and popliteal veins). Reflux due to incompetent valves in the superficial venous system is the most common form of venous insufficiency, and may or may not have associated symptoms. In most patients however, varicose veins with symptoms such as heavy, burning, itchy, aching or painful legs are reported. In addition, varicose veins may be complicated by edema, thrombophlebitis, venous ulceration and chronic skin changes.1,2
The ultimate goal of any treatment regimen is to eliminate sources of reflux in order to control the progression of the disease, improve symptoms, promote ulcer healing, and prevent recurrence or a combination of these. The best therapeutic results are based on two hemodynamic principles: the abolishment of the highest point of reflux and the elimination of the incompetent and dilated venous segments.
Closing the great saphenous vein (GSV) is a recognized procedure in reducing the effects of venous valvular insufficiency. Traditionally, this has been accomplished by surgical ligation and stripping. Although this technique resulted in a durable treatment, it also resulted in significant perioperative morbidity.2,3 More recently endovenous methods have been used. These techniques use thermal ablation with laser or radiofrequency heating.3 Some of the challenges with the thermal ablation methods include complications related to the thermal injury of the treated vessel and surrounding tissue, which may result in skin burns, injury to the saphenous nerve or thrombotic and inflammatory events.1Sapheon, Inc. has developed a novel system for closing the GSV with an endovenous technique, using a catheter system for access and a dispensing unit for application of a cyanoacrylate tissue adhesive for closure of the GSV.
Tissue adhesives represent a group of compounds that can be applied locally for a variety of indications, including hemostasis, wound closure, and fistula repair. The main classes of tissue adhesives currently utilized in surgery include cyanoacrylates, fibrin glues, and thrombin. Cyanoacrylates are used widely outside of the United States and in the United States as tissue adhesive, a vascular closure agent, and as an intracranial embolic agent for arteriovascular malformations.
Cyanoacrylates are synthetic glues that rapidly polymerize on contact with

water or blood. N-butyl-2-cyanoacrylate (Histoacryl; B Braun, Melsungen, Germany) has been used extensively in surgery for the last 10 years. Another N-butyl-2-cyanoacrylate (Glubran; GEM S.r.l., Viareggio, Italy) was recently approved for endoscopic use in Europe. 2-Octyl-cyanoacrylate (Dermabond; Ethicon, Inc., Somerville, NJ), approved by the Federal Drug Administration for superficial wound closure, is widely used by emergency room physicians, dermatologists, and plastic surgeons.
It is expected that GSV closure for the treatment of incompetent saphenous veins with the Sapheon Closure System will have comparable or better procedure safety and effectiveness, but be less painful than other treatments, and require a shorter recovery period.

Study objective

5.1 Study Objectives
The primary objective for this clinical observational study is to assess the role of the Sapheon Closure System in closure of incompetent great saphenous veins in a routine clinical setting.
5.2 Study Hypothesis
This is an observational study on routine intervention for abolishing GSV reflux. Efficacy and safety (adverse events) will be compared to appropriate literature reports to determine if the results of the treatment of reflux disease with the Sapheon Closure System are consistent with or better than the expectations of the medical community for alternative treatments, specifically Laser Thermal Ablation and Radiofrequency Ablation. Additional comparison points may include measurements of pain and/or length of time to return to work.

Study design

This is an international, multi-center, prospective, single arm, observational, post-market release study designed to record the clinical outcomes of the CE marked Sapheon Closure System for its CE marked approved indications. Subjects who meet the eligibility criteria will be enrolled sequentially. No control arm will be used since efficacy will be determined using the subjects* pre-treatment status as an internal control.

Study burden and risks

Risks include those normally expected for standard vein surgery. Complications are generally rare, not severe, and may require additional procedures to correct.
Following the procedure, subjects will be followed for at least 6 months (and up to 36 months). A total of 7 regular follow-up visits will occur at the following time points: 24-72 hours post-procedure, 30 days post-procedure, 3 months post-procedure, 6 months, 12 months, 24 months, and 36 months

post-procedure. Additional visits will be scheduled if deemed appropriate in the judgment of the Investigator

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age *18 years and * 70 years of age.
* Symptomatic primary GSV incompetence diagnosed by clinical symptoms, with or without visible varicosities, and confirmed by duplex ultrasound imaging.
* CEAP classification of C2, C3 or C4 (see Appendix 10).
* Ability to walk unassisted.
* Ability to attend follow-up visits.
* Ability to understand the requirements of the study and to provide written informed consent.

* GSV on standing pre-procedure Doppler US *3mm and *10mm (maximum diameter).

Exclusion criteria

* Life expectancy < 1 year.
* Regular pain medication.
* Anticoagulation including Heparin or Coumadin.
* Previous DVT.
* Previous superficial thrombophlebitis in GSV.
* Previous venous treatment on target limb.
* Known Hyper-coagulable disorder.
* Conditions which prevent routine vein treatment like:
o Acute disease,
o Immobilization or inability to ambulate, and
o Pregnancy.
* Tortuous GSV, which in the opinion of the Investigator will limit catheter placement. (no 2 primary access sites allowed).
* Incompetent ipsilateral small saphenous or anterior accessory great saphenous vein.
* Known sensitivity to the cyanoacrylate (CA) adhesive.
* Current participation in another clinical study involving an investigational agent or treatment, or within the 30 days prior to enrollment.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2016
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Sapheon Closure System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL38844.094.12