VenaSeal Spectrum: Global, Post-Market, Prospective, Multi-Center, Randomized Controlled Trial of the VenaSeal* Closure System vs. Surgical Stripping or Endothermal Ablation (ETA) for the Treatment of Early and Advanced Stage Superficial Venous Disease.

Published: 17-06-2021
Last updated: 09-04-2024

Randomized Studies (CEAP 2-5): To evaluate the patient*s experience and clinical improvement after treatment with the VenaSeal* system compared to standard of care treatments, surgical stripping or ETA, in the treatment of symptomatic superficial...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Venous varices
Study type	Interventional

Summary

ID

NL-OMON52834

Source
ToetsingOnline

Brief title
VenaSeal Spectrum study

Condition

- Venous varices

Synonym
symptomatic superficial venous disease

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Endothermal Ablation (ETA), Superficial Venous Disease, Surgical Stripping, VenaSeal Closure System

Outcome measures

Primary outcome

For the CEAP 2-5 Randomized Studies, the primary objectives are to compare the VenaSeal* system to surgical stripping and ETA regarding patient experience and satisfaction, through a validated, patient-centered 2-part venous treatment satisfaction questionnaire (VenousTSQ-early [VenousTSQe] and VenousTSQ-status [VenousTSQs]) at 30 days, and the ability to achieve elimination of clinically relevant superficial truncal disease in the target veins at the index procedure.

For the VLU Study, the primary objective is to evaluate time to ulcer healing through 12 months.

Primary Endpoints

The CEAP 2-5 Randomized Studies have three primary endpoints comparing the VenaSeal* system to surgical stripping or ETA.

1.Peri-procedural patient satisfaction as measured by a validated, patient-centered venous treatment satisfaction questionnaire (VenousTSQe) at 30 days.

2.Patient satisfaction as measured by a validated, patient-centered venous treatment satisfaction questionnaire (VenousTSQs) at 30 days.

3.Elimination of clinically relevant superficial truncal disease in each target vein at the time of index procedure as measured by the percentage of target vein length successfully treated.

The primary endpoint for the VLU Study is time to ulcer healing, calculated through healing confirmation and verified by an independent core laboratory through 12 months.

Secondary outcome

The key secondary objectives are to compare the VenaSeal* system to surgical stripping and ETA in achieving the anatomical closure of superficial truncal veins at 6 months, and the ability to return to work post-index procedure.

The secondary objective of the study is to evaluate the VenaSeal* system in the treatment of symptomatic venous reflux in the superficial truncal veins.

Specific areas of analysis include: effectiveness, safety, healthcare utilization, patient experience, and treating physician experience.

In addition, secondary objectives in the VLU Study include ulcer healing rate,

ulcer recurrence, and ulcer-free time.

Data supporting the following endpoints will be collected for both the CEAP 2-5 Randomized Studies as well as the VLU Study. When appropriate, data will be evaluated for the CEAP 2-5 Randomized Studies to compare the VenaSeal* system to surgical stripping or ETA. Data may also be pooled for all VenaSeal* system subjects from the CEAP 2-5 Randomized Studies and VLU Study as appropriate. Data from VenaSeal vs. Surgical Stripping Study will be collected through the 12 months visit.

Effectiveness secondary endpoints

Data supporting the following endpoints will be collected for both the CEAP 2-5 Randomized Studies as well as the VLU Study. When appropriate, data will be evaluated for the CEAP 2-5 Randomized Studies to compare the VenaSeal* system to surgical stripping or ETA. Data may also be pooled for all VenaSeal* system subjects from the CEAP 2-5 Randomized Studies and VLU Study as appropriate. Data from VenaSeal vs. Surgical Stripping Study will be collected through the 12 months visit.

Effectiveness secondary endpoints

Data supporting the following endpoints will be collected for both the CEAP 2-5 Randomized Studies as well as the VLU Study. When appropriate, data will be evaluated for the CEAP 2-5 Randomized Studies to compare the VenaSeal* system

to surgical stripping or ETA. Data may also be pooled for all VenaSeal* system subjects from the CEAP 2-5 Randomized Studies and VLU Study as appropriate. Data from VenaSeal vs. Surgical Stripping Study will be collected through the 12 months visit.

Effectiveness secondary endpoints

1.Anatomic closure of primary target vein at 30 days, and 12, 24, 36, 48 and 60 months:

•For subjects treated with the VenaSeal* system or ETA it is defined as DUS showing vein closure along the entire treated vein segment with no discrete segments of patency exceeding 5 cm.

• For subjects treated with surgical stripping this is defined as absence of refluxing or residual vein at 30 days and 12 months only.

2.Anatomic closure of target vein at 30 days, and 6, 12, 24, 36, 48 and 60 months:

•For subjects treated with the VenaSeal* system or ETA this is defined as DUS showing vein closure along the entire treated vein segment with no discrete segments of patency exceeding 5 cm.

•For subjects treated with surgical stripping this is defined as absence of refluxing or residual vein at 30 days, 6 and 12 months only.

3.Fechnical success of each target vein immediately post-index procedure :

•For subjects treated with the VenaSeal* system or ETA this is defined as DUS

showing vein closure along the entire treated vein segment with no discrete segments of patency exceeding 5 cm.

•For subjects treated with surgical stripping this is defined as absence of refluxing or residual vein.

4.Reintervention of any target vein (including primary target vein) through 60 months, assessed at each follow-up visit. Subjects enrolled in the VenaSeal vs. Surgical Stripping Study will be followed through the 12 months visit only.

5.Time to reintervention of any target vein (including primary target vein) through 60 months, as measured by the time between the index procedure and the first reintervention procedure. Subjects enrolled in the VenaSeal vs. Surgical Stripping Study will be followed through the 12 months visit only.

Study description

Background summary

Please see protocol page 24 section 4.1 for the extensive background of the study

Study objective

Randomized Studies (CEAP 2-5): To evaluate the patient*s experience and clinical improvement after treatment with the VenaSeal* system compared to standard of care treatments, surgical stripping or ETA, in the treatment of symptomatic superficial venous disease (CEAP 2-5). Patient-centered outcomes, vein closure, ability to return to work, and clinical improvement will be

measured after treatment of symptomatic venous reflux in the superficial truncal veins by the VenaSeal* system or the comparator treatments.Additionally, in a separate single-arm study, CEAP 6 patients with at least one active venous leg ulcer will be enrolled, treated with the VenaSeal* system and evaluated for wound healing. This study will complement the available clinical evidence for the VenaSeal* system
There will be up to approximately 500 subjects enrolled in the VenaSeal Spectrum Study. Approximately 375 subjects will be enrolled in CEAP clinical classifications 2-5 in the Randomized Studies (108 subjects in VenaSeal vs. Surgical Stripping Study and about 264 subjects in VenaSeal vs. ETA Study)), and up to 125 CEAP 6 subjects with will be treated with the VenaSeal* system. Enrollment of the VenaSeal vs. Surgical Stripping Study was closed on 22-Feb-2022. All subjects participating in the VenaSeal vs ETA Study or in the VLU Study (CEAP 2-6) will be followed up to 60
months post-index procedure, all subjects participating in the VenaSeal vs. Surgical Stripping Study will be followed up to 12 months post-index procedure.

VLU Study (CEAP 6): To evaluate the patient*s experience and clinical improvement after treatment with the VenaSeal* system in the treatment of active venous leg ulcer (VLU) (CEAP 6) subjects.

Study design

Global, post-market, prospective, multi-center randomized controlled trial of patients with symptomatic superficial venous disease, with a single arm embedded ulcer subgroup.
There will be approximately 500 subjects enrolled in the VenaSeal Spectrum Study. Approximately 375 subjects will be enrolled in CEAP clinical classifications 2-5 in the Randomized Studies (108 subjects in VenaSeal vs. Surgical Stripping Study and about 264 subjects in VenaSeal vs. ETA Study), and up to 125 CEAP 6 subjects with (VLUs) will be treated with the VenaSeal* system.Enrollment of the VenaSeal vs. Surgical Stripping Study was closed on 22-Feb-2022.

Intervention

Please see protocol section 10, from pg 51-80

Study burden and risks

Regarding study participation, subjects are not put at any additional risk for participating in the study, as compared to being treated with the VenaSeal* system, through ETA, or a surgical stripping treatment as part of their routine care. Subjects for whom it is unethical to be randomized to one of the treatment arms, should not be included in this study. Subjects who are included

in this study will receive an increased level of care from their physicians as a result of participation, specifically additional follow-up visits and AE assessments.
Given the available information above, the data support that for use in the treatment of lower extremity symptomatic varicose veins, the probable benefits of treatment with the VenaSeal* system, treatment with ETA, or treatment through a surgical stripping procedure outweigh the probable risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Patient is >=18 years of age
2. Patient has venous reflux in superficial truncal vein(s) (e.g., GSV, SSV, accessory saphenous veins) with CEAP category 2 (symptomatic) or CEAP category 3, 4a, 4b, 5, 6 based on the American Venous Forum CEAP classification (2004),

appropriate for treatment, as confirmed by DUS
3. Eligibility for treatment:
• VenaSeal vs ETA Study: Patient is eligible for treatment with the VenaSeal* system and ETA
• VenaSeal vs Surgical Stripping Study: Patient is eligible for treatment with the VenaSeal* system and surgical stripping
• VLU study: patients should be eligible for treatment with the VenaSeal* system.
4. Treatable refluxing segment of target vein(s) 10 cm in length or longer
5. Patient has a target vein diameter of >=3 mm throughout the intended treated segment of the target vein as measured by DUS while patient is standing
6. Patient is willing and capable of complying with specified follow-up evaluations at the specified times
7. Patient has an ability to understand the requirements of the study and to provide informed consent

Exclusion criteria

1. Patient has a known history of allergic sensitivities (including but not limited to cyanoacrylate adhesives), or any other condition, which in the opinion of the investigator may make the patient more susceptible to cyanoacrylate adhesive hypersensitivity
2. Patient has known deep vein obstruction in the target limb, as identified by the site*s standard of care
3. Patient has abnormal pulse exam or ABI <0.8
4. Patient has acute superficial thrombophlebitis
5. Patient requires any non-target vein treatments in the contralateral or ipsilateral limb, or any other surgical procedure 30 days pre-procedure and through 3 months post-procedure
6. Patient has any co-morbid conditions, which in the investigator*s opinion may interfere with the patient*s compliance with study visits and procedures, or may confound interpretation of study data (e.g., congestive heart failure Class III and IV, non-ambulatory patients, severe hepatic dysfunction, life expectancy < 1 year)
7. IFU contraindications:
• VenaSeal vs. ETA Study: Patient has VenaSeal* system and ETA product*s IFU contraindication(s)
• VenaSeal vs Surgical Stripping Study: Patient has surgical stripping and VenaSeal* system IFU contraindication(s)
• VLU study: Patient has VenaSeal* system IFU contraindication(s)
8. Patient is non-ambulatory
9. Patient is a female of childbearing potential who may be pregnant or breastfeeding at the time of the index procedure
10. Patient belongs to a vulnerable population per investigator's judgment or patient has any kind of disorder that compromises his/her ability to give

written informed consent and/or to comply with study procedures
11. Patient is currently participating in an investigational drug or device study when the data collected could be conflicting or biased due to participation in another study
12.Patient has documented COVID-19 infection currently or within the past 3 months . Patient is not completely recovered from past COVID-19 infection, per physician's discretion.
13. VLU Study: Patient has target ulceration identified to be of non-venous etiology, as confirmed by the independent core laboratory
14. VLU Study: Patient has target circumferential ulceration that cannot be captured in a single photograph (any ulcer curvature around the leg that goes out of sight)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-09-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	VenaSeal closure system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-06-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT03820947
CCMO	NL73627.091.20