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Evaluation of the safety and feasibility of foam injection combined with laser treatment for varicose veins

Submission date	Recruitment status	[ ] Prospectively registered
21/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/03/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/07/2023	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic venous disease (CVD) occurs when the wall and/or valves in the leg veins do not work effectively, making it difficult for blood to return to the heart from the legs. CVD is a common cause of leg pain and swelling and is commonly associated with varicose veins (swollen and enlarged veins). Although CVD is frequently associated with the great saphenous vein, the small saphenous vein (SSV) is responsible for about 15% of varicose vein cases. Foam sclerotherapy involves injecting foam into a vein to close it. Endovenous laser ablation uses heat from a laser to reduce varicose veins. This study aims to determine if adding foam sclerotherapy to endovenous laser ablation can improve the venous clinical severity score and reduce the need for secondary treatment and reduce recurrence.

Who can participate?
Patients aged 18 to 86 years with varicose veins of the SSV

What does the study involve?
Participants are randomly allocated to one of two groups. Half of the participants will receive foam sclerotherapy combined with endovenous laser ablation. The other half will receive endovenous laser ablation alone. All participants will be evaluated 1 year later for recurrence and the need for additional follow-up interventions.

What are the possible benefits and risks of participating?
The patients may benefit from an effective treatment of their varicose veins that is less invasive. The study does not involve any major risks as the treatment is very well known.

Where is the study run from?
Sakurabashi Watanabe Hospital (Japan)

When is the study starting and how long is it expected to run for?
September 2016 to September 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Satoshi Watanabe
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
21-33

Study information

Scientific Title
In adult patients with small saphenous vein incompetence, how effective is transluminal injection of foam sclerotherapy added to endovenous laser ablation compared to endovenous laser ablation alone in controlling post-procedure outcome during 1-year follow-up time?

Study objectives
To compare concurrent foam sclerotherapy through the access sheath (transluminal injection of foam sclerotherapy [TLFS]) combined with endovenous laser ablation (EVLA) with EVLA alone in

terms of safety, need for secondary interventions, and 1-year venous clinical severity score (VCSS) changes in patients with chronic venous insufficiency and small saphenous vein (SSV) incompetence.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/04/2016, Sakurabashi Watanabe Hospital Medical Ethics Committee (Umeda 2-4-32, Kita-ku, Osaka, 530-0001, Japan; +81 (0)6 6341 8660; i_oka@watanabe-hsp.or.jp), ref: 21-33

Study design
Single-centre interventional double-blinded randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Varicose veins

Interventions
Current interventions as of 30/09/2022:

Patients with symptomatic primary SSV reflux are randomised by sealed envelopes to either TLFS with EVLA or EVLA alone. Secondary intervention using the same foam concentration is performed if reflux of the targeted tributary is detected on Doppler ultrasound or if the varicosities remained clinically visible. Post-procedure evaluations are performed to assess vein occlusion, sclerotherapy-related deep vein thrombosis, and endovenous heat-induced thrombosis at 1 day, 1 week, 1 month, and 12 months. Outcomes assessed at 1 year include the presence of residual or recurrent reflux, clinical recurrence, sensory complications, the need for secondary interventions, and venous clinical severity score (VCSS) changes. All adverse events that occurred during or <30 days after procedures were considered to be procedure-related. The American Venous Forum/Society of Interventional Radiography classification system grades complications as minor or major. The outcome assessments were performed by an attending physician who was unaware of the actual intervention.

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Previous interventions:

Patients with symptomatic primary SSV reflux are randomised by flipping a coin to either TLFS with EVLA or EVLA alone. Secondary intervention using the same foam concentration is performed if reflux of the targeted tributary is detected on Doppler ultrasound or if the varicosities remained clinically visible. Post-procedure evaluations are performed to assess vein occlusion, sclerotherapy-related deep vein thrombosis, and endovenous heat-induced thrombosis at 1 day, 1 week, 1 month, and 12 months. Outcomes assessed at 1 year include the presence of residual or recurrent reflux, clinical recurrence, sensory complications, the need for secondary interventions, and venous clinical severity score (VCSS) changes. All adverse events that occurred during or <30 days after procedures were considered to be procedure-related. The American Venous Forum/Society of Interventional Radiography classification system grades complications as minor or major. The outcome assessments were performed by an attending physician who was unaware of the actual intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 26/07/2023:

Venous clinical severity score (VCSS) improvement at 1 day, 1 week, 1 month, and 1 year

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Previous primary outcome measure:

The presence of residual or recurrent reflux measured using colour Doppler ultrasound at 1 day, 1 week, 1 month, and 1 year

Secondary outcome measures
Current secondary outcome measures as of 26/07/2023:

All reported ipsilateral superficial venous re-interventions due to the symptomatic residual or recurrent reflux of truncal SSVs and/or tributary veins or patient complaints of visible varicosities with cosmetic concerns or any reported procedural complications. These included sensory complications, endovenous heat-induced thrombosis (EHIT), superficial thrombophlebitis, sclerotherapy-related DVT / pulmonary embolism, and allergic or anaphylactic reactions.

Previous secondary outcome measures:

1. Sclerotherapy-related deep vein thrombosis (DVT) measured using colour Doppler ultrasound at 1 day, 1 week, 1 month, and 1 year
2. Endovenous heat-induced thrombosis (EHIT) measured using colour Doppler ultrasound at 1 day, 1 week, 1 month, and 1 year
3. Sensory complications measured by asking participants about their recovery status and complications at 1 day, 1 week, 1 month, and 1 year
4. The need for secondary interventions measured using colour Doppler ultrasound at 1 day, 1 week, 1 month, and 1 year

5. Clinical outcome measured using the venous clinical severity score (VCSS) at 1 day, 1 week, 1 month, and 1 year

Overall study start date
08/09/2016

Completion date
02/09/2021

Eligibility

Key inclusion criteria
Patients with unilateral or bilateral varicose veins of the SSV with clinical class C2 to C6 disease using the clinical, etiologic, anatomic, and pathophysiologic (CEAP) classification

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
191 patients (214 legs)

Total final enrolment
134

Key exclusion criteria
1. Recurrent varicose veins after previous surgery, EVLA, or foam sclerotherapy
2. A hypersensitivity reaction to sclerotherapy
3. Acute deep vein thrombosis (DVT) or a history of DVT
4. Severe lower limb ischaemic disease (lower extremity arteriosclerosis obliterans, thromboangiitis obliterans, acute arterial embolism, or Raynaud syndrome)
5. Coagulation disorder
6. Indications for simultaneous EVLA in both the GSV and SSV

Date of first enrolment
08/09/2016

Date of final enrolment
02/09/2020

Locations

Countries of recruitment
Japan

Study participating centre
Sakurabashi Watanabe Hospital
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Sponsor information

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Hospital/treatment centre

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ROR
https://ror.org/03rx00z90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/11/2023

Individual participant data (IPD) sharing plan
The datasets generated or analyzed during the current study during this study will be included in the publication of the subsequent results

IPD sharing plan summary
Published as a supplement to the results publication