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Endovenous laser ablation using different wavelengths and fibers

Submission date	Recruitment status	[ ] Prospectively registered
16/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/03/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/03/2014	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Endovenous laser treatment involves having a catheter inserted into your vein and using an ultrasound scan to guide it into the correct position. A tiny laser is passed through the catheter and positioned at the top of your varicose vein.
The laser delivers short bursts of energy that heat up the vein and seal it closed. The laser is slowly pulled along the vein using the ultrasound scan to guide it and allowing the entire length of the vein to be closed.
810nm endovenous laser ablation is an effective treatment for varicose veins but pain after the procedure is a common side effect .
The aim of this study is to find out whether the new 1470 nm endovenous laser ablation system improves treatment for patients with varicose veins compared with the 810nm laser.

Who can participate?
Patients aged 18 and above diagnosed with varicose veins.

What does the study involve?
Patients are randomly allocated to one of three different laser wavelengths and fibres for endovenous varicose vein treatment.

What are the possible benefits and risks of participating?
Less pain bruising and tightness after the procedure and better work productivity.
There is no risk of participating. Endovenous laser is a minimally invasive standard procedure. There will be no additional treatments in one of the groups. There are no reports in the literature of an increased risk of an ELVeS treatment. It is therefore not expected that the patient who participates in this study are at any extra risk.

Where is the study run from?
The study is run from Bergman Clinics, Netherlands.

When is the study starting and how long is it expected to run for?
The study started in August 2013 and is expected to run until August 2014.

Who is funding the study?
Bergman Clinics, Netherlands.

Who is the main contact?
Dr BCVM Disselhoff

Contact information

Type(s)
Scientific

Contact name
Dr Ben Disselhoff

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized clinical trial comparing 810 nm and 1470 nm endovenous laser ablation for varicose veins

Study objectives
To investigate whether the 1470 nm diode laser improves the outcome of endovenous laser ablation for patients with primary varicose veins due to duplex documented reflux of the great saphenous vein (GSV).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized single-blinded single-centre single-operator (BD) clinical 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Varicose veins, great saphenous vein, endovenous laser

Interventions
Patients are randomized to one of three groups:

Group 1: receives EVLA with the 810 nm laser and a never touch fiber
Group 2: receives ELVeS with the 1470 nm laser using a bare fiber
Group 3: receives ELVeS with the 1470 nm laser using a 2ring radial fiber

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary safety outcome: Pain: The patients registered an overall pain score on a visual analogue scale from 0 (no pain) to 100 (worst imaginable pain) for the first 14 days after treatment. The research nurse recorded the pain score and a statistician calculated the scores.
Primary efficacy outcome: Abolition of reflux: Abolition of GSV reflux is confirmed by Duplex ultrasound. The diagnostic duplex criteria for abolition of reflux of the treated GSV segment. GSV is defined as the absence of retrograde flow lasting longer than 0.5 s on Duplex scanning. Measured at 6 weeks and at 3 months.

Secondary outcome measures
Secondary safety outcomes:
1. Tightness: The patients registered a tightness score on a visual analogue scale from 0 (no pain) to 100 (worst imaginable tightness) for the first 14 days after treatment. The research nurse recorded the tightness score and a statistician calculated the scores.
2. Bruising/ecchymosis: The patients registered a bruising score on a visual analogue scale from 0 (no pain) to 100 (worst imaginable bruising) for the first 14 days after treatment. The research nurse recorded the bruising score and a statistician calculated the scores.
3. Work Productivity and Activity Impairment (WPAI) score: Work and activity outcomes were

assessed using the Work Productivity and Activity Impairment GH questionnaire. All four domains of the WPAI questionnaire were assessed: 1. Absenteeism; 2. Presenteeism (reduction in productivity at work); 3. Overall work impairment; 4. Overall activity impairment. Measured at 14 days after treatment.
4. Deep vein thrombi (DVT)/pulmonary embolism (PE): All patients were requested to contact us if symptoms of DVT or PE developed. The diagnostic duplex criteria for thrombosis were abnormal or lack of vessel wall compressibility, intraluminal thrombus formation (mass) and absence of flow in the deep venous system.

Secondary efficacy outcome:
1. Occlusion of the vein: Occlusion of the treated GSV vein segment is confirmed by Duplex ultrasound. The diagnostic duplex criteria for occlusion of the treated GSV is demonstrated by its complete
occlusion or obliteration, confirmed by Duplex ultrasound. Measured at 6 weeks and 3 months.
2. Improvement in AVVVS (Aberdeen Varicose Vein Severity Score): a disease-specific quality of life measure, is recorded by the research fellow and calculated by a statistician. Measured at 6 weeks and 3 months.

Overall study start date
01/08/2013

Completion date
01/08/2014

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Patients with varicose veins stages C3-C6, Ep,AS3,Pr (according to CEAP classification criteria), with primary symptomatic unilateral varicose vein due to duplex documented reflux of the GSV
3. Duplex documented GSV criteria: refluxtime > 0.5s and GSV located in the saphenous compartment
4. Duplex documented endovenous procedure criteria: GSV diameter between 3 and 20 mm, absence of thrombus mass in the target vein

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Concomitant reflux of anterior accessory great saphenous vein (AAGSV), posterior accessory great saphenous vein (APGSV) and superficial accessory great saphenous vein (ASGSV)
2. GSV not located in the saphenous compartment
3. Extreme tortuosity
4. Patients with fibromyalgia and RA, active, and/or in the family
5. Pregnancy and breastfeeding
6. Documented deep venous thrombosis/pulmonary embolism
7. Previous surgical treatments

Date of first enrolment
01/08/2013

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Singel 1 F
BUSSUM
Netherlands
1402NN

Sponsor information

Organisation
Bergman Clinics (Netherlands)

Sponsor details
Prof Bronkhorstlaan 10
Bilthoven
Netherlands
3723MB

Sponsor type
Hospital/treatment centre

Website
Http://www.bergmanclinics.nl

ROR

https://ror.org/00z1c3x88

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bergman Clinics (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration