ISRCTN51995477 https://doi.org/10.1186/ISRCTN51995477

Randomised controlled trial comparing foam sclerotherapy, alone or in combination with endovenous laser therapy, with conventional surgery as a treatment for varicose veins

Submission date
25/02/2008

Recruitment status
No longer recruiting

Registration date
29/02/2008

Overall study status
Completed

Last Edited
05/09/2019

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Up to 15% of men and 25% of women at some point in their life develop swollen and enlarged veins called varicose veins. This results in about 95,000 operations being performed each year in the NHS in England alone. There is considerable variation across the UK in accessing treatment for varicose veins, and also to the type of treatment offered. The most common treatment offered is surgery, which involves stripping out the veins under general anaesthetic. Recently, new treatments have been developed for treating varicose veins. These are called minimally invasive techniques as they can be given under local anaesthetic and so avoid the scars and bruising associated with surgery. They may also allow a quicker return to normal daily activities and work, more rapid treatment for a greater number of people, and result in fewer complications. They also allow expensive operating theatre time to be freed up. The two most common types of minimally invasive treatment are foam sclerotherapy and endovenous laser ablation. Foam sclerotherapy involves injecting special foam into your veins that scars the veins and seals them closed. Endovenous laser treatment involves having a tiny laser inserted into your vein which delivers energy that heats up the vein and seals it closed. Both techniques have been classified as safe to use in the NHS, although we have been advised to carefully monitor any side effects that might occur following foam sclerotherpy. Despite good short-term results, success in the long term is unclear. This study will assess this and determine the need for a second course of treatment.

Who can participate?
Patients aged over 18 with varicose veins

What does the study involve?
Participants are randomly allocated to be treated with either surgery, foam sclerotherapy or both endovenous laser ablation and foam sclerotherapy. Participants are followed-up for six months initially (and then for up to 5 years) and are asked about their varicose veins, their general health and any visits to their GP or hospital about their varicose veins.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Aberdeen Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
June 2008 to May 2011

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Julie Brittenden
j.brittenden@abdn.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Julie Brittenden

Contact details
c/o Vascular Department
Ward 36
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN
-
j.brittenden@abdn.ac.uk

Additional identifiers

Protocol serial number
HTA 06/45/02

Study information

Scientific Title
Randomised controlled trial comparing foam sclerotherapy, alone or in combination with endovenous laser therapy, with conventional surgery as a treatment for varicose veins

Study objectives
Foam sclerotherapy is more cost-effective in terms of incremental cost per quality-adjusted life year compared to surgery or laser therapy.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/064502
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/51448/PRO-06-45-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration - submission pending as of 25/02/2008

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Arm 1: Foam sclerotherapy
Arm 2: Foam sclerotherapy + endovenous laser therapy
Arm 3: Conventional surgery

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following will be assessed at 6 months:
Primary patient outcome:
1. Disease specific: Aberdeen Varicose Vein Questionnaire
2. Generic: EuroQol (EQ-5D), the 36-item Short Form health survey (SF-36)

Primary economic outcome:
3. Incremental cost per quality adjusted life year (QALY)

Key secondary outcome(s))
1. Costs to the health service and patients and any subsequent care
2. Technical success of venous intervention at 6 weeks and 6 months
3. Clinical success of venous intervention at 6 weeks and 6 months
4. Disease-specific and generic quality of life at 6 weeks
5. Behavioural recovery

Completion date
31/05/2011

Eligibility

Key inclusion criteria
1. Adult patients (aged over 18 years old)
2. Those who are referred to the surgical out-patient department for treatment of primary varicose veins with symptomatic (CEAP [Clinical, Etiological, Anatomical, Pathological elements] classification grade 2 or above) primary long or short saphenous main stem incompetence (reflux >1 second on duplex scanning)
3. Suitable for day case treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
798

Key exclusion criteria
1. Current deep vein thrombosis
2. Deep venous incompetence
3. Acute superficial vein thrombosis
4. Allergy to sclerosant
5. Pregnancy or breastfeeding
6. History of hypercoagulability
7. Arterial disease (ankle brachial pressure index <0.8)
8. Inability to mobilise post-procedure
9. Needle phobia
10. Long or short saphenous vein less than 3 mm in diameter or greater than 15 mm and tortuous veins that are considered to be unsuitable for endovenous laser ablation (EVLA) due to difficulties in passing the guide wire
11. Inability to complete study questionnaires

Date of first enrolment
01/06/2008

Date of final enrolment
31/05/2011

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/09/2014		Yes	No
Results article	results	01/11/2014		Yes	No
Results article	results	01/04/2015		Yes	No
Results article	5-year results	05/09/2019		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes