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Ultrasound guided foam sclerotherapy combined with sapheno-femoral ligation compared to surgical treatment of varicose veins

Submission date
15/12/2010

Recruitment status
No longer recruiting

Registration date
20/04/2011

Overall study status
Completed

Last Edited
22/03/2012

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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Study information

Scientific Title

Randomised contolled trial of ultrasound guided foam sclerotherapy combined with sapheno-femoral ligation compared to surgical treatment of varicose veins

Study objectives
The hypothesis of this study is that duplex guided foam sclerotherapy in combination with saphenofemoral ligation under local anaesthesia may save costs and treatment time and be more acceptable for patients than ligation and stripping of the greater saphenous vein and phlebectomies. This is because there is no need for general anaesthesia and it is a less invasive procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ealing and Mental Health Ethics Committee approved in 2003 (ref: LREC 03/04)

Primary study design
Interventional

Study design
Single centre randomised controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic venous insufficiency

Interventions
Group surgery:
1. High saphenofemoral ligation
2. Strip to the knee
3. Multiple phlebectomies

Group surgery and foam:
High saphenofemoral ligation under local anaesthesia and foam sclerotherapy under ultrasound guidance.

Both arms had 5 years treatment/ follow up (some patients up to a max of 7 years)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Patient recovery period
2. Quality of life

Outcome measured up to 7 years maximum

Key secondary outcome(s)
1. Frequency of complications
2. Cost of the treatment

Outcome measured up to 7 years maximum

Completion date
01/02/2007

Eligibility

Key inclusion criteria
Primary symptomatic varicose veins involving the great saphenous system in patients whom had had no previous treatment for varicose veins and who were suitable for day case surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Primary varicosities involving the short saphenous vein
2. Patients with previous surgery or sclerotherapy for varicose veins
3. Previous deep vein thrombosis (DVT)
4. Risk factors for DVT
5. Coagulopathy
6. Peripheral vascular disease
7. Known allergy to anaesthetic or sclerosing agents
8. Previous iatrogenic allergic reaction
9. Malignancy
10. Pregnancy

Date of first enrolment
01/07/2003

Date of final enrolment
01/02/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ealing Hospital
Middlesex
United Kingdom
UB1 3HW

Sponsor information

Organisation
Ealing Hospital NHS Trust (UK)

ROR
https://ror.org/0380w8h49

Funder(s)

Funder type
Industry

Funder Name
STD Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2012		Yes	No