ISRCTN62966817 https://doi.org/10.1186/ISRCTN62966817

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/04/2011	**Overall study status** Completed	
Last Edited 22/03/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr George Geroulakos

Contact details
Ealing Hospital
Uxbridge Road
Southall
Middlesex
United Kingdom
UB1 3HW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G Geroulakos

Study information

Scientific Title
Randomised contolled trial of ultrasound guided foam sclerotherapy combined with saphenofemoral 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)

Study design
Single centre randomised controlled parallel group 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
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 measure
1. Patient recovery period
2. Quality of life

Outcome measured up to 7 years maximum

Secondary outcome measures
1. Frequency of complications
2. Cost of the treatment

Outcome measured up to 7 years maximum

Overall study start date
01/07/2003

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

Age group
Adult

Sex
Both

Target number of participants
60

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
England

United Kingdom

Study participating centre
Ealing Hospital
Middlesex
United Kingdom
UB1 3HW

Sponsor information

Organisation
Ealing Hospital NHS Trust (UK)

Sponsor details
Research and Development Office
Pasteur Suite, 8th Floor
Uxbridge Road
Southall
Middlesex
England
United Kingdom
UB1 3HW
gay.bineham@eht.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.ealinghospital.nhs.uk

ROR
https://ror.org/0380w8h49

Funder(s)

Funder type
Industry

Funder Name
STD Pharmaceuticals (UK)

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

Study outputs

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