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Randomised controlled comparison study of endoleuminal Laser versus Foam Sclerotherapy in Treatment of Varicose veins

Submission date 28/09/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/09/2007	**Overall study status** Stopped	
Last Edited 18/10/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Bruce D Braithwaite

Contact details
E Floor, West Block
Department of Vascular Surgery and Endovascular Surgery
Derby Road
Nottingham
United Kingdom
NG7 2UH
+44 01159249924
bruce.braithwaite@nuh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0192187950

Study information

Scientific Title

Acronym
LAVA

Study objectives
1. Primary research objectives:
1.1 What is the level of pain in both procedures?
1.2 What is the extend of bruising after the procedure?
1.3 What is the level of patient satisfaction?
1.4 What is the number of treatment episodes required?

2. Secondary research objectives:
2.1 What is the time to perform the procedure?
2.2 What is the recurrence rate?
2.3 What is the complications?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions

Varicose vein surgery is a common operation with between 400 and 500 cases performed each year in Nottingham. Traditional Varicose vein surgery for the long saphenous system (LSV) consists of a high ligation, involving a cut in the groin and multiple avulsions, dealing with the varicosities in the legs. This requires general anaesthesia and is performed as a day case or inpatient treatment with one night in hospital. For patients, traditional surgery results in pain, extensive bruising, limited mobility and a delayed return to normal activity lasting up to six weeks, although more usually only two weeks. Surgery needs to be performed by surgeons who have achieved competence in the procedure. Recently, new methods for treating varicose veins have been introduced into the independent healthcare sector. These give patients a choice of procedures and some allow varicose veins to be treated without general anaesthesia. In addition, patients report less pain, bruising and an early return to normal activity. These new procedures are endoluminal thermal ablation (VNUS), endovenous laser therapy (EVLT), venocuff valve reinforcement and Varicofoam therapy. The NHS modernisation programme aims to increase the use of day case surgery, enhance patient choice , Increased day case activity in Nottingham can be performed in the new diagnostic and treatment centre (DTC). The aim of this study is to compare the latest treatments for varicose veins using established outcome assessments verified by previous studies performed in the department of vascular surgery at the QMC.

Study design:
The study comprises randomised study comparing different approaches to the treatment of long and short saphenous disease. Patients will be given a copy of the information sheet. They will be given time to consider their decision and when they wish to enter, they will be asked to sign the study consent form. A copy will be given to patient, one will be placed in their clinical notes and one will be kept in Mr Braithwaite's office at the QMC. Data will be recorded on an established venous database. In all of the component parts of the study, one leg will be chosen at random for the treatments that are to be compared. All patients will have pre-procedure duplex examination of their legs to confirm the anatomy of their varicose veins. The stage of Venous disease (CEAP classification) will be recorded. Before the selected treatment, digital photographs of the patients' legs will be taken according to our established methodology. Patients will be asked to complete visual analogue scales before the procedure to assess their perception of pain and bruising in their legs. For 10 days after the procedure, patients will be asked to keep a diary record of pain, bruising and activity. Between 5 and 10 days after the procedure, patients will be visited by a trained nurse who will note any complications and repeat the digital photographs. Patients will be seen between 6 weeks and 3 months post-operatively for a clinic review as is our normal practice. At this visit, photographs will be taken again to assess residual varicosities (varicose veins not fully treated). Patients will be asked specific questions about the quality of their treatment and any complications (satisfaction, pain, numbness, infections, scarring). During the same time interval a duplex scan will be performed to objectively assess the completeness of treatment. As close to one year, two years and five years after treatment, patients will be asked to attend the vascular laboratory at QMC for clinical and duplex assessment. The study will be completed 1 year after final patient recruitment.

Outcome assessment:
This study is based on within patient comparison and therefore each component requires only a few patients. Power studies
are included in the description of each component of the study. Endpoints:
1. Primary - Pain, bruising and patient satisfaction, number of treatment episodes required.
2. Secondary - time to perform procedure, time in hospital, cost, recurrence rates. Complications.
Methods of recording endpoints: Visual analogue scales, timings, economical valuation.

The trial was stopped as funding was withdrawn.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain, bruising and patient satisfaction, number of treatment episodes required.

Secondary outcome measures
1. Time to perform procedure, time in hospital, cost, recurrence rates
2. Complications

Overall study start date
20/10/2006

Completion date
01/10/2007

Reason abandoned (if study stopped)
Lack fo funding

Eligibility

Key inclusion criteria
Men and women requesting treatment for bilateral varicose veins who present to the Vascular Clinics at the Queen's Medical Centre, City Hospital and independent hospitals within Nottinghamshire (UK).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients under 21 and over 80 years
2. Patients without varicose veins
3. Patients wishing to have only one leg treated
4. Patients who does not speak English or need interpretation

Date of first enrolment

20/10/2006

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
E Floor, West Block
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Nottingham University Hospitals NHS Trust (UK), NHS R&D Support Funding

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