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Comparison study for treatment of great saphenous vein varicosities

Submission date 17/08/2011	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/03/2012	**Overall study status** Stopped	
Last Edited 20/12/2017	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Varicose veins develop when the small valves inside the veins stop working properly, causing blood to flow backwards and collect in the vein, eventually causing it to be swollen and enlarged (varicose). They most commonly develop in the legs and feet. Surgery is considered the “gold standard” of treatment and is a common procedure. In recent times alternatives such as radiofrequency ablation (RFA) and endovenous laser therapy (EVLT) have been considered. They have the benefit of being less invasive, lead to a quicker return to normal activity after surgery, and are increasing in popularity with patients. Treatment involves using energy either from high-frequency radio waves (RFA) or lasers (EVLT) to seal the varicose veins. Currently we do not know which treatment is best. EVLT, although effective, is associated with increased pain after the operation. RFA traditionally was a lengthy procedure but in recent years segmental RFA was introduced to decrease procedure time. Limited evidence currently exists looking at segmental RFA. RFA has been shown to be safe and fast but we need to make a comparison with established treatments to measure its effectiveness.

Who can participate?
Patients aged 18-80 due to undergo elective procedures for varicose veins.

What does the study involve?
Participants will be randomly allocated into two groups: those who will undergo radiofrequency treatment and those who will receive laser therapy for leg varicose veins. Both procedures will be performed following uniform guidelines. Patients will not undergo any additional treatment procedure. A separate group incorporating patients who undergo surgery will also exist; this will be an observational group only: study participants will not be put into this group. Participants will undergo clinical assessment and examination as part of our routine practice. Following the procedure patients will be followed up after one week, one month and three months. This will involve evaluation of pain, bruising, tenderness, patient quality of life and at three months vein occlusion.

What are the possible benefits and risks of participating?
The study will involve additional follow up from that normally provided. This will comprise of three clinic appointments with clinical assessment and a questionnaire. This does have the

disadvantage of inconvenience to patients but the further benefit of close patient contact and continuity of care with the hospital team. With the results of this study we will be able to better choose which procedure to adopt for our patients in the future.

Where is the study run from?
The study would be based within the single centre vascular unit at Wirral University Teaching Hospital (UK).

When is the study starting and how long is it expected to run for?
We anticipate the trial will start during November 2011 and run for about one year.

Who is funding the study?
Investigator initiated and funded (Mr Ramasubramanyan Chandrasekar).

Who is the main contact?
Kate Hancorn
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Endovenous laser therapy, radiofrequency ablation and segmental surgical avulsions of the great saphenous vein in the treatment of varicosities: a randomised control trial

Study objectives
Radiofrequency ablation of the great saphenous vein is more painful than endovenous laser therapy of the vein.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled single-center 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 vascular disease

Interventions
Total of 84 patients - 28 patients randomised to each of the EndoVenous LAser therapy (EVLA) and RadioFrequency Ablation (RFA) groups, and 28 recruited to the surgery group).

Patients attend clinic with varicose veins: at this time they are assessed, including a routine duplex imaging scan, and evaluated for treatment. Patients decide from this point, if appropriate, to proceed to an elective procedure. Once the decision has been made to have treatment for the veins the trial will be fully discussed with the patient. We will use the information already obtained from duplex scanning, the Venous Clinical Severity Score (VCSS) will be calculated and CEAP classfication deduced. They will leave the clinic appointment with written information and contact details should they wish to discuss any details further. When they attend for the elective procedure the trial will again be discussed; this will be approximately four weeks following initial consultation allowing sufficient time for the research participant to consider all available options. Following valid consent the procedure will be performed.

Follow up appointments will be at one week, one month and three months to assess patient progress. Pain experienced will be measured using a visual analogue scale. Tenderness and bruising also assessed at this visit. A patient questionnaire will be provided in order to assess effect on patient quality of life. At the three month visit duplex examination will be performed to look for treatment result and vein occlusion.

Intervention Type
Procedure/Surgery

Primary outcome measure
Assess post operative pain, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain), following treatment of the great saphenous vein varicosities to evaluate efficacy of the treatments for varicose veins.

Secondary outcome measures
1. Evaluate the three different treatments: surgery, radiofrequency ablation and laser treatment
2. Assessment of post procedure bruising: presence and extent
3. Patient quality of life will be assessed by means of a questionnaire
4. Post procedure VCSS will also be calculated

Overall study start date
01/11/2011

Completion date
01/11/2012

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Subjects will be selected from those already undertaking an elective procedure for varicose veins
2. Patients aged 18 to 80 years old
3. Participants must be sufficiently mobile following procedure and have the availability to attend follow up
4. Patients must give informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
A sample size of 84 patients

Key exclusion criteria
1. Patients who are pregnant or breast feeding
2. Patients with evidence of thrombus within the great saphenous vein

Date of first enrolment
01/11/2011

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Merseyside
United Kingdom
CH49 5PE

Sponsor information

Organisation
Wirral University Teaching Hospital (UK)

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05cv4zg26

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Mr Ramasubramanyan Chandrasekar)

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