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VNUS vs ClariVein for varicose veins

Submission date	Recruitment status	[X] Prospectively registered
22/07/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/05/2017	Circulatory System	

Plain English summary of protocol

Background and study aims

Varicose veins are a common problem and affect about 30-40% of the population at some point in their lives. The severity of varicose veins varies from purely cosmetic to severe leg ulceration and it has been shown that treating varicose veins results in significant improvements in quality of life. New minimally invasive treatments have become available in the last decade - these are termed endovenous ablation treatments (inside-the-vein closure treatments). These techniques either use energy to heat the inside of the vein, causing it to stick together and block off (ablation). Alternatively, we can use chemicals (glues) to stick the vein together (pharmacological occlusion) or a combination of a mechanical tip and chemicals to stick the vein together and block it off (pharmaco-mechanical ablation). All of these treatments seal off the problem vein. In this trial we are using either radiofrequency heat ablation or pharmaco-mechanical ablation to seal off the vein. Endovenous radiofrequency ablation treatment uses heat energy delivered via a probe inserted into the vein in order to treat the long veins in the leg, and has been shown to be safe and effective. The device is called VNUS ClosureFAST. Pharmacomechanical ablation treatment uses a rotating metal tip to 'scratch' the lining of the vein and inject a liquid chemical called sclerosant into the vein at the same time. The sclerosant causes the vein to stick together. This technique has also been shown to be safe and effective. The device is called ClariVein. The varicosities (or lumpy veins) are removed via small cuts (<0.5 cm long) in the skin termed 'phlebectomies' or 'avulsions', performed at the same time as the long veins are treated. Foam sclerotherapy can be used as an alternative to avulsions. This uses a special chemical made into foam, which is injected into the varicose veins using small needles. As with liquid sclerosant it causes the vein to stick together and block off (sclerose).

Who can participate?

Any male or female over the age of 18, with symptomatic varicose veins (long or short saphenous veins).

What does the study involve?

We will ask you about your medical history and fill in a questionnaire with you. You will be assigned a trial number and your treatment plan will be randomly allocated. The allocation will not affect the standard of your care. It will decide the treatment device used. Both are standard care treatment options. You will then have endovenous treatment of your varicose veins with avulsions. The treatment will use either VNUS radiofrequency thermal ablation (heat treatment) or ClariVein pharmacomechanical ablation (mechanical and chemical treatment). This will be

carried out under local anaesthetic. You will be asked to score the level of pain experienced during the procedure using a special scale. You will then be asked to keep a patient diary for the 30 days after treatment. 30 days after your treatment you will be reviewed in clinic with a further questionnaire and a repeat venous duplex. Six months after your operation you will again be reviewed in clinic with a venous duplex ultrasound of your leg to assess technical success and another questionnaire.

What are the possible benefits and risks of participating?
You are not expected to gain any personal benefit from taking part in this study. However, the information gained may help other people in the future. It is not possible to offer any financial incentive for taking part in the study. There are no specific side-effects, disadvantages or risks from taking part in this study as both treatments offered are standard practice. The differing techniques are utilised throughout the world. The specific risks of varicose vein treatment are the same for all treatments - the most common are bleeding, bruising and infection. This is because cuts are made in the skin and the veins, which would be expected to lead to some bleeding, which is controlled at the operation. Cuts in the skin provide a possible route of entry for infection, which is controlled with antibiotics at the operation and further antibiotics if required. The major complication associated with all varicose vein procedures is a deep vein thrombosis (DVT). This is a clot in the deep veins of the leg (famously called economy class syndrome). This is reduced in the case of endovenous treatment due to reduced to pain post-operatively - patients are often back at work the day after the procedure. Due to the minimally-invasive ('keyhole') technique the risk of serious bleeding is greatly reduced in endovenous treatment and we are able to give a special blood-thinning injection to help reduce the risk of clots in the leg veins.

Where is the study run from?
Imperial College Healthcare NHS Trust and Imperial College (UK)

When is the study starting and how long is it expected to run for?
August 2012 to September 2014

Who is funding the study?
Vascular Insights (USA)

Who is the main contact?
Mr Tristan Lane
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Contact information

Type(s)
Scientific

Contact name
Prof Alun Davies

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P40864

Study information

Scientific Title
Randomised clinical trial comparing VNUS ClosureFAST with ClariVein for varicose veins

Acronym
VVCVV

Study objectives
ClariVein procedure for varicose veins is significantly less painful than radiofrequency ablation under local anaesthetic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London - Chelsea Research Ethics Committee, 21/05/2012, ref: 12/LO/0570
2. Joint Research Office, Imperial College London and Imperial College Healthcare NHS Trust, 03/07/2012, ref: JRC0HH0431

Study design
Randomised clinical 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Varicose veins, venous disease

Interventions
Treatment arm one is:
VNUS ClosureFast radiofrequency ablation of the incompetent long or short saphenous vein with phlebectomies as per standard published treatment technique.

Treatment arm two is:
ClariVein mechanochemical ablation of the incompetent long or short saphenous vein with phlebectomies as per standard published treatment technique.
There is no medication utilised. The treatment if one sitting in an outpatient procedure.

Follow-up is 6 months in both arms.

Patients will be randomised to receive one of the possible treatment options. Treatments will be completed under local anaesthetic with concomitant phlebectomy if necessary. Randomisation will be via an internet randomisation service.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. A comparison of pain during the procedure measured using a patient-reported visual analogue score (VAS) comparing RFA and ClariVein®
2. Treatments will be performed under local anaesthetic with concomitant phlebectomy to treat varicosities
3. Pain during the procedure will be measured using a validated patient-reported Visual Analogue Score (VAS)

Secondary outcome measures
1. Quality of life at 30 days and 6 months measured using the Aberdeen Varicose Vein Severity Score (AVVSS)
2. Occlusion rates at 30 day and 6 months
3. Clinical success, including residual varicosities, complications and recurrence rates at 6 months
4. Improvements in generic quality of life using the EQ-5D at 30 days and 6 months
5. Clinical improvements measured using the Venous Clinical Severity Score (VCSS) at 30 days and 6 months
6. Time to return to work and normal activities assessed using a 30-day patient diary
7. A comparison of the cost-effectiveness of the treatment regimes will be made

Overall study start date
31/08/2012

Completion date
08/09/2014

Eligibility

Key inclusion criteria
1. Adults over 18 years of age
2. Symptomatic long or short saphenous vein reflux < 0.5 seconds on colour duplex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

Key exclusion criteria
1. Current DVT
2. Recurrent varicose veins
3. Arterial disease (ABPI <0.8)
4. Veins less than 3 mm in diameter
5. Hypercoagulability
6. Patients who are unwilling to participate
7. Inability or unwillingness to complete questionnaires

Date of first enrolment
22/01/2013

Date of final enrolment
08/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Charing Cross Hospital
London
United Kingdom
W6 8RF

Study participating centre
Northwick Park Hospital
London North West Hospitals NHS Trust
Watford Rd
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Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Joint Research Compliance Office
Imperial College London and Imperial College Healthcare NHS Trust
Charing Cross Hospital
Fulham Palace Road
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W6 8RF

Sponsor type
University/education

Website
http://www.imperial.ac.uk/clinicalresearchgovernanceoffice

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Vascular Insights (USA)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Tristan Lane (tristan.lane@imperial.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	early results	01/02/2016		Yes	No
Results article	final results	01/03/2017		Yes	No