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VNUS® ClosureFAST™ Ablation versus Laser for Varicose Veins

Submission date	Recruitment status	[_] Prospectively registered
27/11/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2011	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRO1037

Study information

Scientific Title
VNUS® ClosureFAST™ Ablation versus Laser for Varicose Veins (VALVV): a randomised clinical trial

Acronym
VALVV

Study objectives
Radiofrequency ablation using VNUS® ClosureFAST™ will result in significantly less post-operative pain and a greater improvement in quality of life in comparison to laser ablation.

As of 11/08/2009 this record has been updated to indicate that this trial has now closed to recruitment. The end of recruitment date was 30/06/2009. Follow-up will continue until 31/01/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charing Cross Research Ethics Committee gave approval on 6th May 2008 (ref: 08/H0711/19)

Study design
Prospective randomised single-blind clinical trial, single centre

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
Varicose veins

Interventions
1. Endovenous radiofrequency ablation 6-month follow-up duration
2. Endovenous laser ablation 6-month follow-up duration

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Average pain score at day 3 and day 10 following the procedure measured using an ungraduated visual analogue score (VAS) 0 = no pain, 10 = worst pain imaginable for 10 days following the procedure.

Secondary outcome measures
1. Use of analgesia, measured at 10 days
2. Improvement in quality of life using the Aberdeen Varicose Vein Questionnaire (AVVQ), the 12-item Short Form (SF-12) and the Specific Quality of Life and Outcome Response - Venous (SQOR-V) questionnaires pre-operatively and at 6 weeks post-intervention
3. Abolition of reflux at 6 months measured using colour duplex
4. Improvements in venous refill times using digitial photoplethysmography, measured at 6 weeks and 6 months
5. Clinical improvement measured using the CEAP, Venous Clinical Severity Score (VCSS) and Venous Disability Score (VDS), measured at 6 weeks and 6 months
6. Return to normal activities and or work
7. Complications, assessed throughout the duration of the patient participation (6 months)

Overall study start date
07/07/2008

Completion date
31/01/2010

Eligibility

Key inclusion criteria
1. Adults aged over 18 years, either sex
2. Venous reflux of the great saphenous vein

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

Key exclusion criteria

1. Patients unfit for general anaesthesia
2. Current deep vein thrombosis
3. Previous venous surgery
4. Significant peripheral vascular disease/Ankle Brachial Blood Pressure Index (ABPI) less than 0.8

Date of first enrolment
07/07/2008

Date of final enrolment
31/01/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
4 East Department of Vascular Surgery
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
c/o Gary Roper
Research Governance Manager of Imperial College
Clinical Reserach Governance Office, G02
Sir Alexander Fleming Building
Exhibition Road
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website

http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Mason Medical Research Foundation (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	01/06/2010		Yes	No
Results article	results	01/02/2011		Yes	No