

VNUS® ClosureFAST™ Ablation versus Laser for Varicose Veins

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|--|---|---|
| Submission date 27/11/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 03/12/2008 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 16/03/2011 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

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 digital 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 Research 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 |