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Vein ablation versus conventional surgery for varicose veins

Submission date	Recruitment status	[ ] Prospectively registered
08/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/02/2010	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
2003/190

Study information

Scientific Title
A randomised controlled trial of Radiofrequency Ablation of the long saphenous vein versus Conventional Saphenofemoral disconnection and stripping in the treatment of varicose veins

Acronym
RACS

Study objectives
Radiofrequency ablation has the potential to improve the outcome of patients undergoing surgical treatment for varicose veins due to superficial venous incompetence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Newcastle and North Tyneside Local Research Ethics Committees on the 1st December 2003. Please note that the sponsor and funder of the trial at the time of ethics approval was Mantis Surgical Ltd (UK).

Study design
Randomised controlled trial using web-based method

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Varicose veins of lower limbs

Interventions
1. Radiofrequency ablation
2. Conventional saphenofemoral disconnetion and stripping

Both procedures are to be performed under general anaesthetic during a single operation. Based on their allocation patients would either receive radiofrequency ablation of their long saphenous vein or stripping of their long saphenous vein. Both groups will undergo multiple stab avulsions or phlebectomies as deemed necessary to complete the operation in the same setting. Both groups are expected to be followed up for five years.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Elimination of long saphenous vein reflux and elimination of truncal varicosities. Measurement of outcomes will be carried out at the end of one week, six weeks, one year and five years.

Secondary outcome measures
1. Time to return to normal activities and work
2. Quality of life, estimated using Aberdeen Varicose Vein Questionnaire, Venous Insufficiency Epidemiologic and Economic Study of Quality-of-Life and Symptoms (VEINES-QOL/Sym) questionnaire, 36-item short form health survey (SF-36) and EuroQOL-5D generic questionnaires

Measurement of outcomes will be carried out at the end of one week, six weeks, one year and five years.

Overall study start date
01/04/2004

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Patients aged 18 - 70 years, both sexes
2. Varicose veins due to isolated long saphenous vein incompetence proven on duplex scan
3. Requiring surgery
4. Long saphenous vein suitable for radiofrequency ablation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Associated short saphenous and deep vein incompetence
2. Pregnancy
3. Patients with pacemaker or defibrillator

Date of first enrolment
01/04/2004

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Vascular Surgeon
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
VNUS Medical Technologies UK Ltd (UK)

Sponsor details
Kenneth Dibben House
Enterprise Road
Southampton Science Park
Chilworth, Hampshire
United Kingdom
SO16 7NS

Sponsor type
Industry

Website
http://www.vnus.com/uk

ROR
https://ror.org/020hbh524

Funder(s)

Funder type
Industry

Funder Name
VNUS Medical Technologies UK Ltd (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	01/01/2010		Yes	No