

# Vein ablation versus conventional surgery for varicose veins

<b>Submission date</b> 08/11/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/02/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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 disconnection 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?
<a href="#">Results article</a>	results	01/01/2010		Yes	No