

Ambulatory Varicosity avUlsion Later or Synchronised (AVULS)

Submission date 26/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/04/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Alun Davies

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

P34317

Study information

Scientific Title

Ambulatory Varicosity avulsion Later or Synchronised (AVULS): a randomised trial

Acronym

AVULS

Study hypothesis

Radiofrequency ablation with concomitant phlebectomy will result in an improvement in quality of life 6 months, reduce the need for further procedures and will be more cost effective than sequential phlebectomy or foam sclerotherapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Brighton and Sussex Research Ethics Committee approved on 21/03/2011, REC Reference Number 11/H1107/3
2. Joint Research Office, Imperial College London and Imperial College Healthcare NHS Trust approved on 30/03/2011, Reference Number JROHH0210

Study design

Randomised 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 below to request a patient information sheet

Condition

Varicose Veins

Interventions

1. Simultaneous or delayed avulsion of superficial varicosities in the context of endovenous radiofrequency ablation of refluxing truncal veins
2. Avulsions will be delayed by 6 weeks post initial procedure if in delayed group
3. Followed up after 1 year

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Disease specific quality of life at 6 months using the Aberdeen Varicose Vein Questionnaire (AVVQ)

Secondary outcome measures

1. The need for further procedures over the 6 month period
2. Generic quality of life assessed using the EQ-5D
3. Cost effectiveness of the treatment strategies
4. Anatomical success assessed with colour duplex at 6 months
5. Level of depression assessed using Center for Epidemiologic Studies Depression Scale (CES-D)
6. Return to work and normal activities
7. Clinical disease severity assessed using the Venous Clinical Severity Score (VCSS)

Overall study start date

01/04/2011

Overall study end date

31/03/2013

Eligibility**Participant inclusion criteria**

1. Consecutive patients who present to the department of vascular surgery at Charing Cross Hospital, who are willing to participate in the study
2. They must have clinical venous disease affecting either the long saphenous or short saphenous veins
3. They must be over the age of 18 and able to give consent for the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

240

Participant exclusion criteria

1. Patients under the age of 18 years
2. Those that are unable to consent
3. Patients with deep venous disease
4. Those unfit for intervention

Recruitment start date

01/04/2011

Recruitment end date

31/03/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Charing Cross Hospital**

London

United Kingdom

W6 8RF

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

AHSC Joint Research Office

Imperial College London and

Imperial College Healthcare NHS Trust

G02 Sir Alexander Fleming Building

South Kensington Campus

London

England

United Kingdom

SW7 2AZ

Sponsor type

University/education

Website

<http://www.imperial.ac.uk/clinicalresearchgovernanceoffice>

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Charity

Funder Name

Graeme-Dixon Charitable Trust (UK) (ref: P34317)

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	01/04/2015		Yes	No