

Ambulatory Varicosity avUlsion Later or Synchronised (AVULS)

Submission date 26/04/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/05/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/04/2015	Condition category Circulatory System	☐ 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

Protocol serial number
P34317

Study information

Scientific Title
Ambulatory Varicosity avUlsion Later or Synchronised (AVULS): a randomised trial

Acronym
AVULS

Study objectives

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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

Key secondary outcome(s)

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)

Completion date

31/03/2013

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key 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

Date of first enrolment

01/04/2011

Date of final enrolment

31/03/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Charing Cross Hospital
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London (UK)

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

Funder(s)

Funder type
Charity

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

Results and Publications

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