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Ambulatory Varicosity avUlsion Later or Synchronised (AVULS)

Submission date
26/04/2011

Recruitment status
No longer recruiting

Registration date
20/05/2011

Overall study status
Completed

Last Edited
30/04/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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

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. 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

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

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
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