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A single-centre study looking at the effect of compression therapy in patients having foam sclerosant injection for varicose veins

Submission date
11/04/2016

Recruitment status
No longer recruiting

Registration date
20/04/2016

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Varicose veins are a common condition, in which the veins (usually on the legs) become swollen and enlarged. It happens when the small valves inside the veins which are designed to make sure blood is travelling in the right direction (back towards the heart) stop working properly, causing blood to leak backwards and collect in the vein. Over the past decade, new minimally invasive treatments ('key hole' procedures) have been introduced. A common type of procedure used is ultrasound guided foam sclerotherapy. This is where special foam is injected into the veins (a process guided using ultrasound scanning) which seal the damage veins closed. This type of procedure is becoming more and more popular as they are associated with fewer complications and a quicker recovery than traditional surgery (to remove the veins). Despite advances in surgical techniques, there is still uncertainty as to the role of compression therapy (wearing tight stockings which squeeze the leg to improve circulation) in the management of varicose veins. The American Venous Forum (an American veins organisation) recommends the use of compression stockings to reduce the risk of clot (haematoma) formation, pain and swelling. The NICE Guidelines have recommended further research into the use of compression stockings as post-procedure intervention because of this lack of evidence. The aim of this study is to compare the effect of compression therapy following foam sclerotherapy.

Who can participate?
Adults with varicose veins suitable for foam sclerotherapy.

What does the study involve?
Participants in both groups undergo foam sclerotherapy of their varicose veins, before being randomly allocated to one of two groups. Those in the first group wear bandages for 24 hours and receive no compression therapy. Those in the second group are asked to wear compression stockings for 1 week following foam sclerotherapy. All participants are given a diary card to rate their pain levels every day for 10 days after their surgery. They are then received two weeks after the procedure in order to fill in questionnaires about their quality of life and undergo a

physical examination to see if there is there is any skin discolouration or inflammation present. Six months after the procedure, participants attend another clinic appointment where they have an ultrasound scan to find out if the surgery has worked and fill in further questionnaires.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Charing Cross Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2015 to December 2017

Who is funding the study?
Chemische Fabrik Kreussler & Co. GmbH (Germany)

Who is the main contact?
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT02655406

Secondary identifying numbers
20419

Study information

Scientific Title
A randomised controlled trial of compression therapy following foam sclerotherapy of varicose vei

Study objectives
Compression therapy following foam sclerotherapy more effective than foam sclerotherapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee North East - Newcastle & North Tyneside 1, 09/09/2015, ref: 15/NE/0314

Study design
Randomized; Interventional; Design type: Treatment, Device

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Varicose veins

Interventions
Patients will be randomised to have compression (group A) or no compression (group B). This will be done by using an online randomisation software (Sealed Envelope Ltd).

The compression therapy used will be Class II compression stockings. The treatment offered will be foam sclerotherapy of varicose veins using either Polidocanol or Sodium Tetradecyl Sulphate (STS) with the concentration used left to the discretion of the clinician.

Group A: Participants will be asked to wear compression stockings for 1 week following foam sclerotherapy.
Group B: Participants will be provided with bandages to wear for 24 hours only, with no further compression afterwards.

Patients in both groups will be followed-up at 2 weeks and 6 months.

Intervention Type
Other

Primary outcome measure
Pain is measured using the visual analogue scale (VAS) at baseline and daily for the first 10 days post procedure.

Secondary outcome measures
1. Quality of life is measured using EQ-5D, AVVQ and CIVIQ at baseline, 2 weeks and 6 months
2. Clinical change is assessed using the VCSS at baseline, 2 weeks and 6 months
3. Degree of phlebitis is assessed at 2 weeks and 6 months
4. Degree of skin discolouration and matting is assessed at 2 weeks and 6 months
5. Patient compliance with the intervention
6. Time taken to return to work and normal activities
7. Occlusion rates at 6 months
8. Cost effectiveness of the intervention

Overall study start date
01/06/2015

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Adults over 18 years of age
2. Varicose veins suitable for foam sclerotherapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 350; UK Sample Size: 350

Total final enrolment
139

Key exclusion criteria
1. Allergic to sclerosant
2. Current DVT
3. Arterial disease (ABPI<0.8)
4. Patients unable to wear compression stockings
5. Patient who are unwilling to participate
6. Inability or unwillingness to complete questionnaires
7. Inability to attend follow-up appointments

Date of first enrolment
10/01/2016

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
Imperial College London
Fulham Palace Road
London

United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London

Sponsor details
-
London
England
United Kingdom
SW7 2AZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Chemische Fabrik Kreussler & Co. GmbH

Results and Publications

Publication and dissemination plan
The study will be presented at international meetings and will be published in peer-reviewed journals.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
Anonymised data is available on request by researchers after the publication of the manuscript from Prof. Alun Davies (a.h.davies@imperial.ac.uk) or Mr Tristan Lane (tristan.lane@imperial.ac.uk). It will be uploaded to a secure data repository for ease of access. Consent for anonymised

analysis of data and consent for publication has been ethically approved and prospectively sought from participants. This data will be stored for 10 years in line with Imperial College London guidelines and will be available from that time. All data should be referenced and cited appropriately.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.1	04/05/2017	18/10/2022	No	No
HRA research summary			28/06/2023	No	No
Basic results	version 23	06/11/2023	06/11/2023	No	No
Results article		01/03/2024	07/05/2025	Yes	No