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Is leg compression needed after heat treatment of varicose veins?

Submission date	Recruitment status	[_] Prospectively registered
10/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2020	Circulatory System	

Plain English summary of protocol
Background and study aims
Leg compression after heat treatment of swollen or enlarged veins is used to reduce the procedure-related side-effects. There is not enough evidence to lend support to the use of leg compression. The aim of this study is to investigate whether leg compression is needed after heat treatment of varicose veins.

Who can participate?
Individuals with enlarged or swollen veins referred to clinics at Royal Bolton Hospital (UK)

What does the study involve?
Patients will be randomly allocated to heat treatment of their veins followed by leg compression or no leg compression.

What are the possible benefits and risks of participating?
Benefits are a reduction in the occurrence of blood clots in veins, pain and inflammation. Risks might be discomfort associated with limb compression and movement restriction.

Where is the study run from?
Royal Bolton Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From February 2015 to February 2016

Who is funding the study?
Royal Bolton Hospital NHS Foundation Trust (UK)

Who is the main contact?
Mr Madu Onwudike
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MO2015a

Study information

Scientific Title
Limb compression after radiofrequency ablation of varicose veins: a randomised controlled study

Study objectives
The outcome in patients who have not worn compression hosiery after radiofrequency ablation of varicose veins is not inferior to those who have worn the hosiery in the post-treatment period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West – Liverpool Central, 18/03/2015, ref: 15/NW/0179

Study design
Single-centre randomised controlled study

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 to request a patient information sheet

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

Interventions
1. Compression after radiofrequency ablation of lower limb varicose veins
2. No compression after radiofrequency ablation of lower limb varicose veins

Intervention Type
Device

Primary outcome measure
Successful obliteration of target vein, assessed with duplex ultrasound scan at 12–14 weeks

Secondary outcome measures
1. Quality of life, assessed with the Aberdeen Varicose Vein Severity Score and the Venous Clinical Severity Score at baseline (on the day of surgery) and at 12 weeks
2. Complications: recorded during patients' follow-up or emergency admissions, including any problems specifically related to stockings from the first post-operative day to 12 weeks
3. Patient's satisfaction, assessed with a patient satisfaction questionnaire
4. Pain, measured with the Visual Analogue Scale questionnaire; completed by the patient during the first post-operative week and collected at the 2 week review
5. Return to normal activities: information obtained by direct questioning at the 2 week interview and reconfirmed at 12 weeks

Overall study start date
01/02/2015

Completion date
01/02/2016

Eligibility

Key inclusion criteria
1. Age 18–90 years old
2. C2 to C6 disease and referred to clinics at Royal Bolton Hospital (UK)
3. Veins anatomically suitable for endothermal ablation

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Total final enrolment
100

Key exclusion criteria
1. Unable to provide informed consent or comply with the study protocol
2. Varicose veins unsuitable for radiofrequency ablation (e.g., very tortuous veins)
3. Pregnancy
4. Lycra allergy
5. Patients who have opted for an alternative method of treatment

Date of first enrolment
05/02/2015

Date of final enrolment
28/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Bolton Hospital NHS Foundation Trust
Minerva Road
Bolton
United Kingdom
BL4 0JR

Sponsor information

Organisation
Royal Bolton Hospital NHS Foundation Trust

Sponsor details
Minerva Road
Fanworth
Bolton
England
United Kingdom
BL4 0JR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/053fx7g25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Bolton Hospital NHS Foundation Trust

Results and Publications

Publication and dissemination plan
Oral presentation at the European Venous Forum and American Venous Forum; original article published in one of the major vascular journals

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	23/10/2020	Yes	No
HRA research summary			28/06/2023	No	No