

Is leg compression needed after heat treatment of varicose veins?

Submission date 10/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/10/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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
madu.onwudike@boltonft.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Mr Madu Onwudike

Contact details

Vascular Surgery
Royal Bolton Hospital
Bolton
United Kingdom
BL4 0JR
+44 (0)1204390105
madu.onwudike@boltonft.nhs.uk

Additional identifiers**Protocol serial number**

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

ROR

<https://ror.org/053fx7g25>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Bolton Hospital NHS Foundation Trust

Results and Publications

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