ISRCTN29102258 https://doi.org/10.1186/ISRCTN29102258

Prospective Randomised Study Of Full Length Compression Stocking And Anti-Embolism Stockings (TEDS) After Varicose Vein Surgery

Submission date 28/09/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/09/2007	**Overall study status** Stopped	
Last Edited 17/04/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Bruce D Braithwaite

Contact details
E Floor, West Block
Department of Vascular Surgery and Endovascular Surgery
Derby Road
Nottingham
United Kingdom
NG7 2UH
+44 01159249924
bruce.braithwaite@nuh.nhs.uk

Additional identifiers

Protocol serial number
N0192187933

Study information

Scientific Title

Study objectives
To find whether full length compression stockings are more effective than anti-embolism stockings when used after varicose vein surgery.

As of 17/04/2012, 'recruitment suspended but expected to resume in 2009' was updated to 'recruitment to start in September 2012'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Obtained 27/02/06.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Some 60 patients who are to have day case surgery on their varicose veins will be asked to take part in this study. At the time of their pre-admission appointment they will be asked to take part and will be given the attached patient information sheet.
Informed consent will be obtained after they have had time to consider the project. Written consent will be confirmed just before their operation when they see the surgeon who will be doing their operation.

After entry to the study, stockings of each type will be randomised using computer generated numbers on a 1:1 basis so that 30 patients will receive anti-embolism stockings and 30 will receive the new style. Patients will be asked to complete a visual analogue scale that measures the discomfort they feel in their legs. Patients will be asked to complete a similar scale for subjective measurement of bruising to their leg. Further information will be collected about stocking slippage and the use of the stockings. Patients will be asked to return to the day case unit two weeks after surgery for a post operative check and for collection of their data sheets and comments. This visit is in addition to their normal appointment at 6 weeks.

Statistical analysis
Categorical data such as slippage will be assessed using the Chi-square test. Variable data such as bruising and pain will be assessed using the Mann Whitney U test for non-parametric data. Sample Size calculation From personal data it is expected that 55% of patients who wear the anti-embolism stocking will experience slippage during their postoperative recovery. Data from Scholl who supply the new style of stocking suggest that a maximum of 20% of patients will experience slippage with their product. For an alpha error of 0.05 and Beta error of 0.2, 50

patients would need to be recruited. There may be a 20% non-compliance rate with follow up so a sample size of 60 has been set. Some 140 people have day case varicose vein surgery each year so recruitment should be complete relatively quickly. Involvement of Non-medical, non-hospital staff. This project has been designed in co-operation with market research experts and consumers that use Scholl stockings bought over the counter at Pharmacies in the UK. Flesch Reading Ease 50.1 Flesch-Kincaid Grade 11.

As of 17/04/2012, the trial was delayed because of changes to the daycase unit. Recruitment is due to start in September 2012.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
We are trying to see if we can improve the care received after the varicose vein surgery we currently offer. We want to know if we can reduce the amount of discomfort the patients get following operation, if we can reduce the amount of pain and bruising, and if we can get the patient back to normal activity earlier than at the moment. We would also like to know if a new type of stocking is as good or better than the one we currently offer, without compromising the standard of care the patients receive. It may also be more cost effective for the NHS.

Key secondary outcome(s))
Not provided at time of registration

Completion date
20/02/2008

Reason abandoned (if study stopped)
Lack of staff/facilities/ resources

Eligibility

Key inclusion criteria
Men and women requesting treatment for bilateral varicose veins who present to the vascular clinics at Queen's Medical Centre.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patient under 21 and over 80 years
2. Patients without varicose veins
3. Patients who do not adequately understand verbal explanations or written information given in English, or who have special communication needs

Date of first enrolment
16/10/2006

Date of final enrolment
20/02/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
E Floor, West Block
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Nottingham University Hospitals NHS Trust (UK), NHS R&D Support Funding

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes