

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

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| Submission date 28/09/2007 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 28/09/2007 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 17/04/2012 | Condition category Surgery | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

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

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

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

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

16/10/2006

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

Age group

Adult

Sex

Both

Target number of participants

60 patients, 30 patients controls and 30 patients with the new type of the stocking. (Amended 17/04/2012: Recruitment to start in September 2012)

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

England

United Kingdom

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)**Funder type**

Government

Funder Name

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

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