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An investigation into the role of compression stockings in the prevention of post-thrombotic syndrome

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/11/2014	Circulatory System	[ ] 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
N0544116504

Study information

Scientific Title
An investigation into the role of compression stockings in the prevention of post-thrombotic syndrome

Study objectives
Do symptom-free patients 6 months after acute deep vein thrombosis (DVT) need to continue with their support stockings?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Deep vein thrombosis (DVT)

Interventions
1. Continued use of compression stocking
2. No further use of compression stocking

Following a deep vein thrombosis (DVT) in the leg, patients are anticoagulated and fitted with a class 2 below knee graduated compression stocking. The latter has been shown to reduce the incidence of painful leg swelling, skin changes and the risk of ulceration arising due to damage to the venous system in the leg. This is referred to as the Post Thrombotic Syndrome (PTS). In the only randomised study to assess this, stockings were worn for a minimum of 2 years and the incidence of PTS halved. In routine daily practice however, patients with few symptoms at 6 months are reluctant to continue with stockings. We are uncertain clinically whether the continued use of stockings in these patients is essential or beneficial. In this study we will randomise patients 6 months after DVT with no or few symptoms in the leg to either continued use of the stocking for a further 18 months, or no stocking. Both groups will be followed on a 6

monthly basis and a clinical assessment of PTS, and stocking compliance will be made at each visit. A venous ultrasound scan will be carried out at entry into the study and at 18 months. From this an objective venous segmental disease score will be recorded.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The principal study outcome measure will be the incidence of PTS in each group.

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/08/2001

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
A total of 100 patients will be randomised by a sealed envelope technique into each group (study total 200).

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
15/08/2001

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

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