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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
The principal study outcome measure will be the incidence of PTS in each group.

Key secondary outcome(s))

Not provided at time of registration

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration