ISRCTN28163533 https://doi.org/10.1186/ISRCTN28163533

A randomised trial to establish the effectiveness of graduated compression stockings (GCS) to prevent post stroke deep venous thrombosis and pulmonary embolism (PE)

Submission date
08/08/2003

Recruitment status
No longer recruiting

Registration date
11/08/2003

Overall study status
Completed

Last Edited
28/01/2011

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.dcn.ed.ac.uk/clots/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0200013

Study information

Scientific Title

Acronym
CLOTS

Study objectives
To evaluate the role of graduated compression stockings in the prevention of post stroke DVT

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular/Stroke

Interventions

Trial 1: Full length GCS and routine care Or Routine care and avoid GCS
Trial 2: Full length GCS and routine care Or Below knee GCS and routine care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Presence of first symptomatic or asymptomatic DVT in the popliteal or femoral veins detected on either of two routine Doppler ultrasound scans (performed at about 7-10 days and 25-30 days) or contrast venography within 30 days of randomisation

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2003

Completion date
30/09/2009

Eligibility

Key inclusion criteria
Immobile patients with an acute stroke, in whom the responsible clinician/nurse is uncertain about either the value of graduated compression stockings (GCS) or the optimal length

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
5500

Key exclusion criteria
1. Patients who, in the opinion of the responsible clinician/nurse, are unlikely to benefit from graduated compression stockings
2. Patients with subarachnoid haemorrhage
3. Patients with peripheral vascular disease, diabetic or sensory neuropathy, where the responsible clinician/nurse judges that stockings may cause tissue necrosis

Date of first enrolment

01/10/2003

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
Australia

Italy

Scotland

United Kingdom

Study participating centre
Dept. of Clinical Neurosciences
Edinburgh
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Sponsor information

Organisation
Medical Research Council (UK)

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scotland Ref.CZH/4/7 (UK)

Funder Name
Chest Heart and Stroke, Scotland Ref. 03/01(UK)

Funder Name
Medical Research Council Ref. G0200531(UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	1. results	06/06/2009		Yes	No
Results article	results	02/11/2010		Yes	No