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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
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

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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

Scotland

Australia

Italy

Study participating centre

Dept. of Clinical Neurosciences
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
Medical Research Council (UK)

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	1. results	06/06/2009		Yes	No
Results article	results	02/11/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes