

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/08/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/01/2011	Condition category Circulatory System	<input type="checkbox"/> 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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EH4 2XU

Sponsor information

Organisation

Medical Research Council (UK)

Sponsor details

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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