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	Recruitment status No longer recruiting	[X] Prospectively registered		
08/08/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
11/08/2003	Completed	[X] Results		
Last Edited 28/01/2011	Condition category Circulatory System	[] Individual participant data		
28/01/2011	Circulatory System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Martin Dennis

Contact details

Dept. of Clinical Neurosciences
University of Edinburgh
Bramwell Dott Building
Western General Hospital
Crewe Road
Edinburgh
United Kingdom
EH4 2XU
+44 (0)131 5371082
msd@skull.dcn.ed.ac.uk

Additional identifiers

Protocol serial number

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

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

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, 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 summaryNot 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