Contact Details
CLOTS Co-ordinating Centre
Neurosciences Trials Unit
Western General Hospital
Crewe Road
Edinburgh EH4 2XU

Tel: 0131 5371082 Fax: 0131 3325150
Email: CLOTS@skull.dcn.ed.ac.uk Web: www.clotstrial.com

Chief Investigator: Prof M Dennis
Chair of TSC: Prof G Venables
Chair of DMEC: Dr J Bamford

Approvals and Registrations

MREC Approval (England, Wales and NI):	08/H0906/137
MREC Approval (Scotland):	08/MREC00/73
R&D Approval (CSP - England & Wales):	9853
R&D Approval (NRS - Scotland):	NRS08/CEO3
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The CLOTS Collaboration

CLOTS 3

(**C**lots in **L**egs **O**r s**T**ockings after **S**troke)

A randomised trial to establish the effectiveness of Intermittent Pneumatic Compression to prevent post stroke deep vein thrombosis (DVT).

Version 2

Protocol Summary

Full protocol available at www.clotstrial.com
24 Hour Helpline 0131 5371082

Introduction to CLOTS 3
Deep vein thrombosis (DVT) is common in immobile patients with a recent stroke. Anticoagulants increase the risk of bleeding which offsets their benefits with respect to DVT prevention. CLOTS Trial 1 has shown that graduated compression stockings (GCS) do not reduce the risk of post stroke DVT. Intermittent pneumatic compression (IPC) reduces the risk of DVT **after surgery** by about 60%. It is relatively safe, compared with anticoagulants, and offers a potentially useful method to reduce the risk of DVT and pulmonary embolism in stroke patients.

A systematic review of all randomised trials of IPC after stroke suggests it is practical, acceptable to patients and may be effective. The CLOTS 3 trial is testing IPC in immobile stroke patients.

Primary Research Questions
Does early and routine application of IPC, in addition to routine care, reduce the risk of above knee DVT in the weeks following an acute stroke?

Is IPC a practical and acceptable treatment for DVT prevention on stroke units?

Inclusion Criteria
Any patient who is admitted to hospital within three days of a clinical stroke and, who is unable to mobilise independently. Patients are ideally randomised on the day of admission (Day 0) but may be enrolled till Day 3 of hospital admission.

Exclusion Criteria (summarised)
- Stroke due to subarachnoid haemorrhage.
- Patients who are unlikely to benefit from IPC (e.g. expected to mobilise within next few days).
- Contraindications to IPC such as local leg conditions, severe arteriosclerosis or massive leg oedema.
- Presence of swelling or other signs of DVT (unless excluded by investigations).

Randomisation
Baseline data will be collected at randomisation using an on line system (www.clotstrial.com) or a 24 hour telephone randomisation service (0131 5372933).

Duration of Treatment
If allocated, the IPC should be continued day and night for 30 days or until a later second screening duplex ultrasound has been performed or the patient is independently mobile or discharged or dies.

Follow up

Day 7 to 10	Compression duplex ultrasound
Day 25 to 30	Repeat compression duplex ultrasound
Discharge or in hospital death	Completion of discharge form
Six months	Centralised follow up

Sample size & Analyses
The trial aims to enrol at least 2000 patients. All analyses will be based on an intention to treat.

Primary outcome
Presence of definite or probable symptomatic or asymptomatic DVT in the popliteal or femoral veins detected on a screening compression duplex ultrasound scan or any symptomatic DVT in the popliteal or femoral veins confirmed on compression duplex ultrasound or contrast venography or MRI direct thrombus imaging within 30 days of randomisation.