ISRCTN25452470 https://doi.org/10.1186/ISRCTN25452470

Randomised controlled trial (RCT) of community management of deep venous thrombosis (DVT) using low molecular weight heparin versus hospital care

Submission date
23/01/2004

Recruitment status
Stopped

Registration date
23/01/2004

Overall study status
Stopped

Last Edited
18/04/2012

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
RGC00325

Study information

Scientific Title

Study objectives
Not provided at time of registration

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 diseases: Thromboembolic disease

Interventions
1. Intervention patients will either be discharged from A&E following confirmation of diagnosis having been given the first dose of low-molecular weight heparin (LMWH) and warfarin, or prior to confirmation of diagnosis having received only the first dose of LMWH. Patients requiring confirmation of diagnosis will be recalled for special clinics established for the study.
2. Control patients will be managed according to the hospital protocol. This normally requires admission for confirmation of diagnosis and commencement of formal anticoagulation with intra-venous heparin. The confirmatory investigation in all cases will be ultrasound.
All patients with positive diagnosis of DVT will be recalled 4 weeks after the initial ultrasound for repeat investigation to determine the resolution of the clot and to complete a Quality of Life questionnaire.

As of 18/04/2012, this study was stopped due to poor recruitment in 1999.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
heparin

Primary outcome(s)

Not provided at time of registration

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

Completion date
31/12/2000

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
All patients aged 18 or over presenting to the A&E Department of the City Hospital, Birmingham, with a clinical diagnosis of Deep Venous Thrombosis (DVT) will be eligible for entry into the study. Patients will be randomised to either an intervention or control arm of the study. 484 patients will be recruited. Assuming a radiological positive diagnosis rate of 50% this will leave 121 patients in each arm of the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
Patients who need to be admitted to hospital for concomitant reasons, patients requiring venography, pregnant and breast feeding women and patients with concurrent malignancy will be excluded.

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2000

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive West Midlands (UK)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes