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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/01/2004	**Overall study status** Stopped	
Last Edited 18/04/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
484

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive West Midlands (UK)

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