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A comparison of enoxaparin and tinzaparin as thromboprophylaxis during pregnancy

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 16/03/2016	**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
N0436130319

Study information

Scientific Title
A comparison of enoxaparin and tinzaparin as thromboprophylaxis during pregnancy

Study objectives
Unpublished data prepared by our department has shown that pregnant women display some resistance to the use of low molecular weight heparins. We would like to compare the use of enoxaparin and tinzaparin in pregnant women who have a previous history of venous thromboembolism, or who have inherited of acquired condition which predisposes them to venous thromboprophylactic doses as recommended by the respective manufacturers and monitoring the effects by using anti factor Xa assays and thromboelastography.

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)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Thromboembolism

Interventions
Randomised controlled trial.
Random allocation to receive:
1. Enoxaparin
2. Tinaparin

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
We propose to compare the coagulation profiles of enoxaparin and tinaparin. We will use TEG and anti Xa activity to monitor effects.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2001

Completion date
01/08/2005

Eligibility

Key inclusion criteria
1. Pregnant patients with moderate risks of venous thromboembolism
2. Patients with history of recurrent miscarriage
3. Patients on low dose aspirin will be included as this has been shown not to adversely affect their TEG variables

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Subjects who have been admitted to hospital and are able to maintain their self catheterization regime
2. Subjects with symptomatic urinary tract infection, who are currently undergoing chemotherapy, radiation or steroid therapy, who self catheterize only once a day

Date of first enrolment
01/08/2001

Date of final enrolment
01/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
Department of Obstetric Anaesthesia
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

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