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# A comparison of enoxaparin and tinzaparin as thromboprophylaxis during pregnancy

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| **Submission date**<br>30/09/2005 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>16/03/2016 | **Condition category**<br>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Unpublished data prepared by our department has shown that pregnant women display some resistance to the use of low molecular weight heparins.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

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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