# A comparison of enoxaparin and tinzaparin as thromboprophylaxis during pregnancy

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Edited Condition category	[] Individual participant data
16/03/2016	Circulatory System	Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

Protocol serial number 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Unpublished data prepared by our department has shown that pregnant women display some resistance to the use of low molecular weight heparins.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 thromboerophylactic 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

#### Study type(s)

Prevention

#### 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(s)

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

### Key secondary outcome(s))

Not provided at time of registration

## 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

#### 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

United Kingdom

England

#### Study participating centre Leeds Teaching Hospitals NHS Trust

Department of Obstetric Anaesthesia Leeds United Kingdom LS9 7TF

# Sponsor information

## Organisation

Department of Health

# Funder(s)

## Funder type

Government

#### Funder Name

Leeds Teaching Hospitals NHS Trust

#### Funder Name

NHS R&D Support Funding

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration