

# A comparison of enoxaparin and tinzaparin as thromboprophylaxis during pregnancy

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/03/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
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Unpublished data prepared by our department has shown that pregnant women display some resistance to the use of low molecular weight heparins.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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**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