

# Effective prevention of blood clots in critically ill patients - part 2

<b>Submission date</b> 25/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/04/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2010-022034-88

**Protocol serial number**  
EudraCT-number: 2010-022034-88

## Study information

**Scientific Title**

Enoxaparin - effective dosage for intensive care patients: a double-blinded, randomised clinical trial - part 2

**Study objectives**

Inadequate dosage of enoxaparin may be a possible explanation for the high failure rate of thromboembolic prophylaxis in intensive care unit (ICU) patients. The administration of higher doses of enoxaparin may give better anti-factor Xa levels in ICU patients and may thereby confer a greater degree of protection against venous thromboembolism.

The first part of our study supported the earlier finding that 40 mg enoxaparin subcutaneously once daily was insufficient for the prevention of venous thromboembolism. The study also pointed to inadequate dose and not the route of administration or disease severity, as the possible explanation for the low anti-Xa activity measured after enoxaparin administration in intensive care patients. These findings require further investigation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Local medical ethics committee (Den Videnskabetisk Komite for Vejle og Fyn), 19/10/2010, project-ID: S-20100089

**Study design**

Prospective randomised double-blinded controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Venous thromboembolism

**Interventions**

Patients will be randomly assigned to four groups by sequentially numbered sealed envelopes to receive one of the following subcutaneous doses of enoxaparin (Clexane®): 40 mg x1, 30mg x2 , 40mg x2 or 1mg/kg x1 for a period of 72 hours. Patients receiving 40 mg (the standard thromboprophylactic dose of enoxaparin) will act as the control group, while patients receiving 30mg x2, 40mg x2 , and 1mg/kg x1 are considered intervention groups. The total duration of treatment and follow-up will be 72 hours.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Enoxaparin

**Primary outcome(s)**

Peak anti-factor Xa levels (peak = 4 hours post-enoxaparin administration). Levels of anti-factor Xa activity will be determined using a validated chromogenic assay kit (COAMATIC Heparin, Chromogenix, Instrumentation Laboratory Company, Lexington, USA) with the substrate S-2732, and the apparatus (STA-R Evolution, Diagnostica Stago, Asnieres, France).

**Key secondary outcome(s)**

1. Antithrombin (AT)
2. Fibrinogen
3. Platelets
4. D-dimer

Measured immediately before, and at 4, 12, 16 and 24 hours after the administration of enoxaparin.

**Completion date**

01/12/2011

**Eligibility****Key inclusion criteria**

1. Consecutive patients admitted to the ICU
2. Aged over 18 years, either sex
3. Minimum stay of greater than 24 hours

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients weighing less than 50 kg or greater than 90 kg
2. Bleeding diathesis
3. In need of an operation within the timeframe of the study
4. Pregnant
5. Requiring continuous veno-venous haemofiltration

**Date of first enrolment**

01/12/2010

**Date of final enrolment**

01/12/2011

## Locations

**Countries of recruitment**

Denmark

**Study participating centre**

**Odense University Hospital**

Odense

Denmark

DK 5000

## Sponsor information

**Organisation**

Odense University Hospital (Denmark)

**ROR**

<https://ror.org/00ey0ed83>

## Funder(s)

**Funder type**

Research council

**Funder Name**

The Danish Society of Anaesthesiology and Intensive Medicines Research Initiative (Denmark)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

19/04/2013

Yes

No