ISRCTN91570009 https://doi.org/10.1186/ISRCTN91570009

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

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| **Submission date**<br>25/11/2010 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>14/03/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>28/04/2015 | **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**
2010-022034-88

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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 Videnskabsetisk Komite for Vejle og Fyn), 19/10/2010, project-ID: S-20100089

## Study design
Prospective randomised double-blinded controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in the web format, please use the contact details below to request a patient information sheet

## 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 measure
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).

### Secondary outcome measures
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.

### Overall study start date
01/12/2010

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
80 patients

### 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
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DK 5000

## Sponsor information

### Organisation
Odense University Hospital (Denmark)

### Sponsor details
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**Sponsor type**
University/education

**Website**
http://www.ouh.dk/wm259883

**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

**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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 19/04/2013 | | Yes | No |