

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

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

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

Denmark

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