

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

Submission date 25/11/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/03/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/04/2015	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Palle Toft

Contact details
Department of Anaesthesia and Intensive Care
Odense University Hospital
Sdr. Boulevard 29
Odense
Denmark
DK 5000
-
palle.toft@ouh.regionssyddanmark.dk

Additional identifiers

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

Protocol serial number
EudraCT-number:

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

Primary study design

Interventional

Study design

Prospective randomised double-blinded controlled trial

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