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

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

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 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

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?

Results article	results	19/04/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes