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Effective prevention of blood clots in critically ill patients

Submission date	Recruitment status	[_] Prospectively registered
03/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/05/2019	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)
2005-002381-10

Protocol serial number
EudraCT: 2005-002381-10

Study information

Scientific Title

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

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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Den Videnskabsetisk Komite for Vejle og Fyn) approved on the 3rd June 2005 (ref: VF-2004-0225)

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 were randomised into four groups/arms to receive one of the following subcutaneous doses of enoxaparin (Clexane®): 40, 50, 60, or 70 mg for a period of 24 hours. Patients receiving 40 mg (the standard thromboprophylactic dose of enoxaparin) acted as the control group, while patients receiving 50, 60, and 70 mg were considered intervention groups. The total duration of treatment and follow-up was 24 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 were 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. Prothrombin time (PT)
3. Activated partial thromboplastin time (aPTT)
4. Thrombin-antithrombin complexes (TAT), determined using an enzyme-immunoassay (Enzygnostâ TAT micro, Siemens, Marburg, Germany)
5. Fibrinogen
6. Platelets
7. D-dimer

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

Completion date
31/03/2009

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
01/02/2006

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Anaesthesia and Intensive Care
Odense
Denmark
DK 5000

Sponsor information

Organisation
Odense University Hospital (Denmark)

ROR
https://ror.org/00ey0ed83

Funder(s)

Funder type
Charity

Funder Name
Professor Sophus H Johansens Foundation (Denmark)

Funder Name
Danielsens Foundation (Denmark)

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?
Basic results			16/05/2019	No	No