

Effective prevention of blood clots in critically ill patients

Submission date 03/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/05/2019	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

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 Videnskabetisk 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 (Enzygnost[®]; 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