ISRCTN33216118 https://doi.org/10.1186/ISRCTN33216118

Thrombin generation after abrupt cessation versus weaning over eight hours of continuous infusion of unfractionated heparin in intensive care unit patients after discontinuation of continuous venovenous haemofiltration

Submission date 22/11/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/11/2006	**Overall study status** Completed	
Last Edited 02/09/2008	**Condition category** Haematological Disorders	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0001; NTR742

Study information

Scientific Title

Acronym
Heparin Rebound

Study objectives
Our hypothesis is that rebound thrombin generation occurs in intensive care unit (ICU)-patients after abrupt cessation of heparin treatment in terms of elevation of coagulation-markers and reduction fibrinolysis-markers; intravenous (IV)-weaning of heparin reduces this rebound thrombin generation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Venovenous haemofiltration

Interventions
Therapeutic protocol:
Prophylactic low molecular weight heparin (LMWH) will not be given within 24 hours of

discontinuation of CVVH. Patients are treated with help of standard guidelines effective in our units. The full medical treatment will be under the discretion of the supervising staff-intensivists who are not directly involved in the study.

Study protocol:
Randomisation will take place using sealed envelopes:
1. In ten patients UFH infusion will be stopped simultaneous to stopping of CVVH
2. In ten patients UFH infusion will be reduced to 50% from the previous infusion rate. After four hours the infusion rate will be reduced again by 50% (25% of original infusion rate) and discontinued four hours later.

Blood samples will be taken at specific intervals to evaluate thrombin generation.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Low molecular weight heparin (LMWH)

Primary outcome measure
Thrombin-antithrombin complexes (TATc)

Secondary outcome measures
1. Activated partial thromboplastin time (aPTT)
2. Anti-factor Xa (anti-Xa)
3. Factor VII/VIIa
4. Tissue factor (TF)
5. Tissue factor pathway inhibitor (TFPI)-antigen
6. TFPI activity
7. Protein C/activated protein C (aPC)
8. Activated protein C sensitivity ratio (aPC-sr)
9. Prothrombin fragment 1.2, ETP (endogenous thrombin potential)
10. Fibrin monomers
11. Soluble thrombomodulin
12. Plasmin-a2-anti-plasmin complexes (PAPc)
13. Plasminogen-activator inhibitor (PAI)

Overall study start date
01/09/2006

Completion date
01/09/2007

Eligibility

Key inclusion criteria

1. Patients scheduled to stop treatment with continuous venovenous haemofiltration (CVVH) because they no longer require it (physicians discretion/local protocol)
2. Age more than 18 years
3. At least 48 hours of CVVH treatment with concomitant continuous infusion of unfractionated heparin (UFH)
4. At least 36 hours of continuous UFH infusion in the last 48 hours prior to inclusion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
1. Patients with known coagulation disorders
2. Patients receiving any anti-coagulant treatment for reasons other than CVVH

Date of first enrolment
01/09/2006

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Intensive Care
P.O. Box 22660
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1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

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