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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr J J H Hofstra

**Contact details**
Academic Medical Centre
Intensive Care Unit
P.O. Box 22660
Amsterdam
Netherlands
1105 AZ
+31 (0)20 5668224
J.J.H.Hofstra@amc.uva.nl

## 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
Amsterdam
Netherlands
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