

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

Registration date

22/11/2006

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

02/09/2008

Condition category

Haematological Disorders

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Thrombin-antithrombin complexes (TATc)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

ROR

<https://ror.org/03t4gr691>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration