Anticoagulation with nadroparin in continuous venovenous hemofiltration (CVVH): extracorporeal clearance and systemic effects of nadroparin

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON29873

Source
ToetsingOnline

Brief title
clearance and systemic effects of nadroparin in CVVH

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
acute renal failure, renal replacement therapy

Health condition

(anti)stolling

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: vakgroep Intensive Care

Intervention

Keyword: hemofiltration, low mulecular weight heparins, nadroparin

Outcome measures

Primary outcome

· anti-Xa activity in plasma and ultrafiltrate

· sieving coefficient of anti-Xa

· clearance of anti-Xa in relation to CVVH dose

Secondary outcome

The course of anti-Xa and ETP in plasma

Relation between anti-Xa and ETP in plasma

Study description

Background summary

The low molecular weight heparin nadroparin is standard anticoagulation for continuous venovenous hemofiltration (CVVH) in many intensive care units in the Netherlands. The drug is administered intravenously in a fixed dose without monitoring of anti-Xa acitivity. The drug is excreted by the kidneys for about 10%. Studies indicate that nadroparin acculmulates in renal insufficiency, increasing the risk of bleeding. While older studies indicate that low molecular weight heparins are not excreted with hemofiltration, a recent small study shows that extracorporeal clearance of the low molecular weight heparin enoxaparin is comparable to normal total plasma clearance.

Study objective

Aim of the present study is to determine
· whether and to what extent nadroparin is excreted by CVVH
· whether the drug accumulates during CVVH as measured by anti-Xa activity and endogenous thrombine potential (ETP)
· whether clearance of nadroparin is related to the dose of CVVH
· the relation between anti-Xa activity and ETP in plasma

Study design

Patients are randomized for CVVH at a rate of 2 L/h or CVVH at a rate of 4 L/h. After one hour, CVVH dose is converted to 4 L/h or 2 L/h respectively. Blood and ultrafiltrate is sampled according to the protocol.

Study burden and risks

There is no risk for the patient. Both modes of CVVH (2 L/h or 4 L/h) are standard treatment. Burden: a total volume of 50 ml of blood is sampled. Blood is sampled form the arterial line and from the CVVH circuit which are both in situ for standard treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

non-surgical patients in the ICU with indication of CVVH for acute renal failure

Exclusion criteria

severe liver failure
active bleeding and need for transfusion

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2006
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13996.067.06