

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

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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 thrombin potential (ETP) · whether clearance of nadroparin...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 molecular 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 activity. The drug is excreted by the kidneys for about 10%. Studies indicate that nadroparin accumulates 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 thrombin 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 from the arterial line and from the CVVH circuit which are both in situ for standard treatment.

## Contacts

### Public

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### Scientific

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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