The effect of pre-versus postdilution and pore size on the clearance of mid size mocules.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON33818

Source
ToetsingOnline

Brief title
Clearance of mid size molecules with hemofiltration.

Condition

- Heart failures

Synonym
shock after cardiac arrest

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Stichting Invensief

Intervention

Keyword: clearance, hemofiltration

Outcome measures

Primary outcome

As a marker for the clearance of smallmolecules, the concentration of creatinin, urea and ADMA will be measured. As a marker for the clearance of the midmolecules, the concentrations of β2-microglobuline en Interleukine-6 will be measured.

The concentrations will be measured in the arterial blood, postfilter blood and in the ultrafiltrate. We will measure the hematocrit in the bloodsamples.

Primary endpoint

Effectivity of the clearance of midmolecules, 15 minutes and 6 hours after start HVHF, expressed as:

o Sieving coefficient

o Concentration filtrate* filtrateflow

Secondary outcome

Secundary endpoints

· Effectivity of the clearance of midmolecules, 12 hours after start HVHF

· Hemodynamics

· Metabolic control

· Other organfailure

Study description

Background summary

In patients with severe shock caused by sepsis or SIRS, high volume hemofiltration during 6-8 hours has a possible positive effect on stabilisation of the circulation and on survival. This effect is found in patients with septic shock with or without renal failure. The circulation in patients after cardiac arrest is often unstable due to a systemic inflammatory response. Laurent compared patients after out of hospital cardiac arrest (ROSC < 60min) treated with the standard therapy (therapeutic hypothermia was not common practice in the study period), treated with HVHF and treated with HVHF and hypothermia. There was a significant better survival in both HVHF groups compared with standard treatment.
In the mentioned studies HVHF was given in dose variable from 4-8 lietrs/hr. In the studies with the higher dosis, the substitutionsfluid are administered in predilutionmodus.
The are large differences in the studies in dosis and in pre- or postdilution modus. Dosis is therefore not comparable in the different studies.

Study objective

The primary goal is investigate the method to achieve the most effective clearance od midmoecules in the first 6 hours of HVHF.
The secondary goal is to determine to wich proportion the clearance of midmolecules due to proteinprecipitation declines in time.

Study design

Prospective randomized controlled trial with patients after cardiac arrest, treated with hypothermia.
Patients will be randomized for HVHF with the conventional filter (cellulose-triacetate, cut-off 60.000 D), high permeable cellulose-triacetate filter (cut-off 100.000 D). In both groups patients will be ramdomized for modus A, B or C

Modus Bloodflowml/min SubstitutionflowPOST ml/u SubstitutionflowPRE ml/u Extra UF
A 240 4100
0 0
B 240 3000
1500 0
C 240 0
5900 0

Intervention

Hemofiltration with one of the earlier mentioned filters in 1 of the 3 modi (A, B, C)

Study burden and risks

The studie patients will receive a CVVH catheter in the vena femoralis or vena jugularis. Theoretically, complications of the insertion of a CVVH catheter are:
· arterial punction and hematoma
· Pneumothorax (only in the vena jugularis position)
The chance of these complications is small in our hospital.
During the first 24 hours, there will be blood and ultrafiltratesamplings. The arterial bloodsamples will be drawn from the arterial catheter, already in place in this catergory of patients. The patient will not notice this at all.
The postfilter bloodsamples will be taken at he side of the hemofiltration machine, as will be done for the ultrafiltrate monsters. There is no burden for the patient. Everey sampling of blood will take 19 ml of bloof=d from the patient.

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

Patients with shock after cardiac arrest, treated with hypothermia

Exclusion criteria

no CVVH available
contra-indication nadroparin

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2009
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2009

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	NL22367.100.08
Other	R-08.31O/HEMOCLEAR