Effect of preload reduction through intermittend hemodialysis or continuous veno-venous hemofiltration on microcirculatory perfusion in patients with chronic kidney failure and critically ill patients

Published: 13-04-2010
Last updated: 02-05-2024

The aim of the study is to observe whether microcirculatory perfusion follows the decrease in preload caused by hemodialysis in a population with an intact and a disturbed microcirculatory autoregulation.

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

Summary

ID

NL-OMON34825

Source
ToetsingOnline

Brief title
Fluid management and peripheral perfusion

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
microcirculatory perfusion, renal replacement therapie

Health condition

intensive care patienten

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hemofiltration, microcirculatory perfusion, preload

Outcome measures

Primary outcome

The main study parameter is the sublingual microcirculatory perfusion.

Secondary outcome

not applicable

Study description

Background summary

The relation between systemic hemodynamic parameters and microcirculatory perfusion is not clear. This is mainly important in patient populations with a disturbed regulation of the fluidbalance, i.e. patients who require renal replacement therapy. It is the question if it is possible to withdraw fluid from the patient without compromising microcirculatory perfusion. We want to investigate the effects on the microcirculatory perfusion in patients with a adequate autoregulation of the microvasculture where the preload is decreased in a short time interval. Additionally we want to study this relationship in a patient population with a disturbed regulation of the microvasculature and where preload is slowly decreased.

Study objective

The aim of the study is to observe whether microcirculatory perfusion follows

the decrease in preload caused by hemodialysis in a population with an intact and a disturbed microcirculatory autoregulation.

Study design

The study will be carried out as a single center observational study on the department of Intensive Care and the outpatient clinic of nephrology of the Erasmus Medical Center.

Study burden and risks

The measurements will not involve risks for the subject. The measurement methods are based on light with harmless wavelength. The measurement probes will only slightly make contact with the sublingual area of the subject. The time of dialysis will not be extended.
In the future patients could benefit from the results, by optimizing the treatment based on individual parameters of microcirculatory perfusion

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

We will include two patientspopulations, firstly patients undergoing chronic intermittend renal replacement therapy in an outpatient clinic setting. Secondly we will include patients admitted to the intensive care unit who receive continuous veno-venous hemofiltration with ultrafiltration. Of both populations we will include 20 patients.
Inclusion criteria for patients receiving chronic intermittend renal replacement therapy:
- Age above 18 yrs
- Admitted for intermittend hemodialysis.;Inclusioncriteria for patients admitted to the intensive care unit who receive continuous veno-venous hemofiltration.
- Age above 18 yrs.
- Clinical indication for continuous veno-venous hemofiltration with ultrafiltration

Exclusion criteria

Exclusion criteria for patients receiving chronic intermittend renal replacement therapy:
- Circumstances making it impossible to perform sublingual measurements, like bleeding of the oral cavity.
- Patients who require no or only small amounts of ultrafiltration during hemodialysis.
;Exclusioncriteria for patients admitted to the intensive care unit who receive continuous veno-venous hemofiltration.
- Circumstances making it impossible to perform sublingual measurements, like bleeding of the oral cavity

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-05-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	13-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL31563.078.10