Mean systemic filling pressure to predict the response to forced fluid removal by continuous renal replacement therapy

Published: 09-09-2013
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To distinguish patients who tolerate fluid removal by CRRT from those who become hemodynamically instable (hypotensive) during this procedure.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON38755

Source
ToetsingOnline

Brief title
Pms fluid removal CRRT

Condition

- Nephropathies

Synonym
renal failure

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: mean systemic filling pressure

Outcome measures

Primary outcome

The mean systemic filling pressure as a predictor for the tolerance of fluid

removal by CRRT.

Secondary outcome

- Pms calculated with an arm stop-flow maneuver

- Peripheral perfusion parameters (CRT, *T, PFI * see paragraph 6.4)

Study description

Background summary

A positive fluid balance is associated with a significant negative influence on survival. Continuous renal replacement therapy (CRRT) can, in addition to removing solutes, also be used to remove large amounts of fluids from the body, especially in patients with a positive fluid balance. However, some patients do not tolerate the removal of fluid: they are not able to shift fluid volume from the interstitial to the intravascular space, leading to a severe decrease in arterial blood pressure. Other patients are perfectly able to shift extra- to intravascular volume and they will remain hemodynamically stable. In this study we want to distinguish these two patient groups by calculating the mean systemic filling pressure before the start of fluid withdrawal.

Study objective

To distinguish patients who tolerate fluid removal by CRRT from those who become hemodynamically instable (hypotensive) during this procedure.

Study design

Prospective observational, diagnostic study.

Intervention

Patients will be subjected to forced fluid removal during continuous renal replacement therapy.

Study burden and risks

There is no additional risk for the patients concerning the extra measurements (non-invasive peripheral perfusion measurements) and data recording. However there is a possible risk that patients become hypotensive. For this reason we defined a MAP lower threshold of 60 mmHg. In the situation where MAP decreases under the lower threshold value, Norepinephrine will be increased to maintain MAP * 60 mmHg.

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

Continuous renal replacement therapy
Hemodynamic stability
Positive fluid balance

Exclusion criteria

Heart Assist devices
Arrhythmias
Heart failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-09-2013
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	NL44518.078.13