Renal fluid responsiveness in oliguric critically ill patients

Published: 22-05-2013
Last updated: 15-05-2024

The objective of this study is to identify potential predictors of renal fluid responsiveness.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON40185

Source
ToetsingOnline

Brief title
Renal fluid responsiveness during oliguria

Condition

- Renal disorders (excl nephropathies)

Synonym
low diuresis, low urine output

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: Acute kidney injury, Critically ill, Fluid therapy, Oliguria

Outcome measures

Primary outcome

The main study parameter is renal fluid responsiveness after fluid therapy.

Fluid responsiveness is defined as an increase in urine output to * 0.5 ml/kg/h

after fluid therapy, and fluid unresponsiveness is defined as persistance of

oliguria after fluid therapy.

Secondary outcome

Hemodynamic, urine and plasma parameters will be collected to identify possible

predictors of renal fluid responsiveness, and patients will be followed till

the 28th day after inclusion or discharge to identify possible differences in

renal outcome between groups.

Study description

Background summary

A decline in urine output below 0.5 ml/kg/h (oliguria) puts critically ill patients at risk to develop acute kidney injury, which is associated with a higher mortality and morbidity rate. To attenuate this risk, patients are often given intravenous resuscitation fluids in an attempt to improve diuresis. However these fluids can accumulate when urine output does not improve, resulting in volume overload, edema and subsequent organ damage, and increase mortality. There are currently no clinical parameters to help physicians predict whether an oliguric patient will be fluid responsive.

Study objective

The objective of this study is to identify potential predictors of renal fluid responsiveness.

Study design

This will be a prospective intervention study in which all subjects receive an

intravenous infusion between 500 ml and 1000 ml of 0.9% saline depending on the clinical situation. Each 500 ml of volume will be infused in 10 to 20 minutes.
All subjects will be measured before treatment and 2 hours after treatment has ended, and followed until discharge or day 28.

Intervention

All subjects will receive an intravenous infusion between 500 ml and 1000 ml of 0.9% saline. Each 500 ml of volume will be infused in 10 to 20 minutes.

Study burden and risks

Fluid therapy is given as treatment for oliguria and fluids will be administered through central or peripheral venous catheters inserted beforehand for standard treatment purposes. Measurements are collected non-invasively and through already inserted catheters for standard treatment purposes. The intended infusion volume is safe in this patient category and participation in this study could lead to direct therapeutic benefit. Incapacitated patients are included because they are a substantial part of the study population and excluding them would lead greatly limit the results.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- * 18 years of age
- Informed consent
- Oliguria for at least 2 consecutive hours
- No diuretics administered in the past 3 hours

Exclusion criteria

- On continuous renal replacement therapy at time of eligibility
- Pregnancy
- Positive fluid balance * 10 L at time of eligibility
- Risk or evidence of pulmonary edema
- Risk or evidence of heart failure or coronary illness
- pH < 7.25 or base excess < -10
- Already included into this study more than 2 times.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2013
Enrollment:	150

Type:	Actual

Ethics review

Approved WMO Date:	22-05-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2014
Application type:	Amendment
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

ID: 28357
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42880.078.13
OMON	NL-OMON28357