Renal fluid responsiveness during oliguria.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28357

Source
Nationaal Trial Register

Health condition

Fluid therapy
Oliguria
Critically ill patients

Vloeistoftherapie
Oligurie
Ernstig zieke patienten

Sponsors and support

Primary sponsor: Department of Intensive Care
Erasmus Medical Center Rotterdam
The Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Fluid responsiveness (urine output to > 0.5 ml/kg/h after fluid therapy). Timepoint: 3 hours.

Secondary outcome

1. Acute kidney injury, Timepoint: 28 days;

2. All-cause mortality, Timepoint: 28 days;

3. Mechnical ventilation days, Timepoint 28 days;

4. Other complications, Timepoint 28 days.

Study description

Background summary

Rationale:

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. Currently there are no clinical parameters to help physicians predict whether an oliguric patient will be fluid responsive, and whether this is beneficial in terms of outcome.

Objective:

The objective of this study is to identify potential predictors of renal fluid responsiveness and whether fluid responsive patients have more favorable outcomes as opposed to fluid unresponsive patients.

Study design:

This will be a prospective intervention study.

Study population:

All critically ill patients admitted to the ICU with oliguria (urine output < 0.5ml/kg/h) for 2 consecutive hours are eligible for inclusion. We will exclude patients with other indications for fluid therapy or unable to safely receive additional fluids.

Intervention:

All subjects will receive an intravenous infusion between 500 to 1000 ml of 0.9% saline or Ringer's Lactate administered in 10 minutes.

Main study parameters/endpoints:

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. Hemodynamic, urine and plasma parameters will be collected to identify possible predictors, and patients will be followed till the 28th day after inclusion or discharge to identify possible differences in renal outcome between groups.

Study objective

Are there any clinical parameters to help physicians predict whether an oliguric critically ill patient will be fluid responsive, and is it beneficial in terms of outcome?

Study design

1. T0 = Inclusion, start measurements;

2. T30(minutes) - T90 = Fluid therapy;

3. T240 = end of measurements;

4. Follow-up until discharge or day 28.

Intervention

All subjects will receive an intravenous infusion of 1500 ml of 0.9% saline during 1 hour.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18 years of age or older;

2. Informed consent;

3. Oliguria for at least 2 consecutive hours;

4. No diuretics administered in the past 3 hours.

Exclusion criteria

1. On continuous renal replacement therapy at time of eligibility;

2. Pregnancy;

3. Positive fluid balance ≥ 10 L at time of eligibility;

4. Risk or evidence of pulmonary edema;

5. Risk or evidence of heart failure or coronary illness;

6. pH < 7.25, base excess < -10, or serum chloride > 110 mmol/l;

7. Already included into this study more than 2 times.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2013
Enrollment:	150
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-04-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40185
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3782
NTR-old	NTR3948
CCMO	NL42880.078.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40185

Study results

Summary results
N/A