Renal fluid responsiveness during oliguria.

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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?

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28357

Bron
Nationaal Trial Register

Aandoening

Fluid therapy
Oliguria
Critically ill patients

Vloeistoftherapie
Oligurie
Ernstig zieke patienten

Ondersteuning

Primaire sponsor: Department of Intensive Care
Erasmus Medical Center Rotterdam
The Netherlands
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

1. T0 = Inclusion, start measurements;

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

3. T240 = end of measurements;

4. Follow-up until discharge or day 28.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-04-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40185
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A