FLUID MANAGEMENT TARGETED ON DIFFERENT VARIABLES OF PERIPHERAL PERFUSION IN PATIENTS ADMITTED TO THE INTENSIVE CARE UNIT.

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We hypothesize that peripheral perfusion targeted fluid management (PPTFM) might prevent excessive fluid administration, leading to less formation of tissue edema, less respiratory dysfunction and shorter duration of mechanical ventilation.

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

Samenvatting

ID

NL-OMON20877

Bron
NTR

Verkorte titel
Peripheral perfusion targeted fluid management

Aandoening

Peripheral perfusion, fluid management, critically ill patients, intensive care unit.

Perifere perfusie, vochttoediening, kritisch zieke patienten, intensive care.

Ondersteuning

Primaire sponsor: Erasmus Medical Centre
Overige ondersteuning: Research fund Intensive Care Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Daily fluid balance;
2. Total fluid balance over Intensive Care Unit admission period.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Currently, fluid administration of critically ill patients is aimed at optimizing conventional hemodynamic parameters such as stroke volume and cardiac output. Fluid is infused repeatedly until patients become “non-responsive”, i.e. cardiac output does not increase anymore. However, the ultimate goal of hemodynamic therapy should be to improve peripheral (i.e. tissue) perfusion. Recently we have shown that:

1. Increasing stroke volume does not always have an effect on peripheral perfusion and;

2. That peripheral perfusion is not impaired when stroke volume can still be increased with fluid infusion.

Furthermore, repeated administration of fluid in order to reach a maximum cardiac output can lead to an enormous accumulation of fluid in the patient. This leads to formation of lung edema and respiratory dysfunction and is associated with prolonged mechanical ventilation and ICU-stay. Recently, techniques have been developed which allow bedside assessment of peripheral perfusion. Although impaired peripheral perfusion was related to worse outcome, these parameters have never been used as target for hemodynamic therapy.

Objective:

To study whether peripheral perfusion targeted fluid management (PPTFM) leads to less fluid administration, improved respiratory function and shorter mechanical ventilation.

Study design:

The study is a pilot study and is designed as a randomized controlled trial. The study will be conducted as a single-center study at the Intensive Care of the Erasmus Medical Center.

Study population:

We aim to include 40 adult patients who are admitted to the Intensive Care with hemodynamic instability (defined as mean arterial pressure < 65 mmHg and an arterial lactate concentration > 3.0 mmol/l) due to severe sepsis and septic shock.

Intervention:

In the intervention group fluid management is targeted on peripheral perfusion parameters while in the control group fluid is administered in order to optimize cardiac output.

Main study parameters/endpoints:

The main study endpoints are daily fluid balance and duration of mechanical ventilation.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

There is a possible risk that in the treatment group the patients will remain hypovolemic. To ensure that this will not occur, fluids will be administrated in this group, irrespective of peripheral perfusion parameters, until cardiac index is 2,5 L/min/m2. Assessment of peripheral perfusion is performed with non-invasive optical techniques that impose no burden to the patient.

Doel van het onderzoek

We hypothesize that peripheral perfusion targeted fluid management (PPTFM) might prevent excessive fluid administration, leading to less formation of tissue edema, less respiratory dysfunction and shorter duration of mechanical ventilation.

Onderzoeksopzet

T1: All measurements will be performed continuously for the first 6 hours; measurements will intermittently be repeated at:

T2: 24hours;

T3: 48 hours, and;

T4: 72 hours after inclusion.

Onderzoeksproduct en/of interventie

Overall, monitoring will be similar for the intervention and the control group.

Parameters of peripheral perfusion will be monitored in both groups (techniques to monitor peripheral perfusion are described in introduction). Septic chock patients require fluid challenges.

The fluid management algorithm of the control group is based on the standard care procedure of our ICU as recommended in guidelines: the patient's fluid status is assessed by performing a fluid challenge with a bolus of 250 ml colloids. When the patients is fluid responsive (i.e. showing an increase in stroke volume > 10%) he will receive an additional bolus of 250 ml of colloids. After each fluid challenge, patients will be revaluated for fluid responsiveness to access need of further fluid administration.

The fluid management algorithm of the intervention group uses identical therapy (i.e. fluids) yet targeted at different endpoints (i.e. peripheral perfusion parameters). After evaluation of peripheral perfusion, only patients with a "bad peripheral perfusion" (i.e. 3 out of 4 criteria considered as bad) will receive a fluid challenge, the same way as in the standard care procedure (i.e. bolus of 250 ml of fluid). After each fluid challenge, patients will be re-evaluated for peripheral perfusion to access further need in fluid challenges. To ensure that no hypovolemia will occur in the intervention group, fluid will be administered irrespectively of peripheral perfusion parameters, if cardiac index falls below a value of 2,5 L/min/m2.

This algorithm will guide fluid administration for the first 6 hours following admission to the ICU. Afterwards, the attending intensivist will be in charge. Measurements will be continued intermittently until 72 hours after admission.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All adult (age > 18 years) patients admitted to the Intensive Care Unit with:

1. Hemodynamic instability due to severe sepsis;

2. A mean arterial pressure < 65 mmHg, and;

3. An arterial lactate concentration > 3.0 mmol/L.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Moribund;

2. Severe coagulation disorder (contraindication for central venous catheter placement);

3. Severe peripheral vascular disease (interfering with peripheral perfusion measurement).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-08-2011
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2836
NTR-old	NTR2977
CCMO	NL34607.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

1. The relation of near-infrared spectroscopy with changes in peripheral circulation in critically ill patients;
2. The prognostic value of the subjective assessment of peripheral perfusion in critically ill patients.