Prediciton of renal response to intravenous fluid administration by passive leg raising and stroke volume variation in critically ill patients.

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The objective of the study is to investigate if predictors of cardiac responsiveness are able to predict a renal response to fluid administration in oliguria.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46898

Source
ToetsingOnline

Brief title
Renal fluid responsiveness

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
Acute kidney injury/acute tubulus necrosis and fluid overload

Health condition

Vloeistofovervulling

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Subsidie van Foreest medical school is verkregen

Intervention

Keyword: oliguria, passive leg raising, renal fluid responsiveness, stroke volume variation

Outcome measures

Primary outcome

The study parameters are: SVV, stroke volume (SV) and cardiac output (CO),

static haemodynamic parameters including SvO2, lactate, diuresis and urinary

indices.

Secondary outcome

For the substudy fluid in the lungs will be assessed by looking at artefacts

with lung ultrasound.

Study description

Background summary

Oliguria is a symptom of volume depletion and a risk for developing acute kidney injury. Acute kidney injury is associated with higher mortality and morbidity in Intensive Care patients. The common treatment is fluid administration and restore possible fluid deficiency, with the risk of fluid overload and edema, particularly when the kidney is damages and non-responsive to fluids. Dynamic parameters as stroke volume variation and its response to passive leg raising (PLR) seems able to predict cardiac fluid responsiveness. Their ability to predict an increase in diuresis to fluid administration however is unknown.

Study objective

The objective of the study is to investigate if predictors of cardiac responsiveness are able to predict a renal response to fluid administration in oliguria.

Study design

This prospective clinical trial concerns the evaluation of well-known predictors of intravascular volume and cardiac responsiveness with renal responsiveness to fluid administration.
Thirty-five patients who are admitted to the Intensive Care Unit with diuresis <0.5 ml/kg/hr after proper initial resuscitation will be analysed during a passive leg raising test and subsequently a fluid infusion of 1 L Ringers lactate in 1 hour, which is part of standard treatment. Stroke volume variation (SVV) by Flotrac/Vigileo (Edwards) and static haemodynamic parameters will be monitored during PLR and during fluid infusion. Diuresis an hour before the PLR and up to 2 hours after fluid infusion will be monitored.

Study burden and risks

Before fluid therapy, patients will be connected to Flotrac/Vigileo (Edwards) by the radial arterial catheter already in place in ICU patients for SVV analysis. No additional placement of catheters is needed.
1.0 liter of Ringers* lactate is the first choice in volume replacement and has been shown to be safe in healthy individuals, does not raise lactate levels and may only give small and transient changes in osmolality. As part of the standard therapy to oliguria, 1.0 liter of Ringers* lactate will be administered in 1 hour, however now in a protocolled manner to analyse this standard treatment.
The results may help to construct a protocol to treat and reverse oliguria and prevent harmful fluid overloading in critically ill patients.
Lung ultrasound is part of standard care on the intensive care and carries no riks.

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

- Mechanically ventilated patients of both gender
- Age 21 years and under 80 years of age
- admitted to the intensive care unit (ICU) with oliguria (<0.5 ml/kg/hr) after the initial resuscitation period at the ICU defined by: no or low increase (less than 25%) in vasopressor medication in the past 2 hour before inclusion and fluid administration less than 500 ml Ringers* lactate per hour.

Exclusion criteria

- medical grounds: the physician requires to deviate from current protocol to adequately treat other life threatening events.
- ethical grounds: e.g. pre-terminal illness
- Loss of blood >100 ml per hour
- relevant alterations in inotropic or vasopressor medication.
- Use of clinically relevant diuretics (furosemide, bumetanide, hydrochloorthiazide during the research protocol)
- a known medical history of significant heart failure requiring daily administration of high dose diuretics.
- pulmonary edema.
- pregnancy
- practical drawbacks

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-04-2015
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	05-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	03-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL50343.094.14