Sublingual microvascular changes in perfused vessel density and boundary region during an intravenous fluid challenge.

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I) Is the infusion of crystalloid fluids in healthy subjects associated with a reduction in microcirculatory perfused vessel density and increase in perfused boundary region? II) Does colloid administration attenuates the crystalloid-induced...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40124

Source
ToetsingOnline

Brief title
CHALLENGE study

Condition

- Other condition
- Therapeutic procedures and supportive care NEC

Synonym
Perioperative fluid load; fluid administration during surgery

Health condition

Volumebelasting

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colloids, Crystalloids, Microcirculation, Tissue perfusion

Outcome measures

Primary outcome

Microcirculatory perfused vessel density (PVD) and perfused boundary region

(PBR) measured using sublingual capillary videoscope imaging.

Secondary outcome

* Intraoperative administered fluid volume, fluid balance, urine output

* Microvascular Flow Index (MFI)

* Microvascular flow heterogeneity

* Hemodynamic parameters (blood pressure, heart frequency, pulse pressure

variation in mechanically ventilated patients, stroke volume, cardiac index.

Study description

Background summary

During anesthesia and surgery, patients receive fluids to maintain system hemodynamics and to compensate for blood loss. Inadequate fluid resuscitation in the intraoperative period may not only result in perioperative hypovolemia or postoperative fluid overload, but may also change the integrity of the vascular wall. Animal studies suggest that the glycocalyx serves as a competent barrier for water and colloids, but may also be damaged by fluid infusion. However, evidence for this phenomenon in patients is limited, which is mainly due to the lack of measurement devices. With the introduction of a novel

technique for evaluation of microvascular changes it has recently become possible to study glycocalyx dimensions in patients. In the present study we will investigate the effects of a fluid challenge on microcirculatory vessel perfusion and the glycocalyx thickness in order to gain more insight in the effects of fluid therapy on microvascular perfusion and the perfused boundary region.

Study objective

I) Is the infusion of crystalloid fluids in healthy subjects associated with a reduction in microcirculatory perfused vessel density and increase in perfused boundary region?

II) Does colloid administration attenuates the crystalloid-induced alterations in the microcirculatory perfused vessel density and increase in perfused boundary region in healthy subjects?

III) What is the relation between the volume of intraoperative fluid infusion and the level of microcirculatory perfused boundary region in patients undergoing surgery?

Study design

An intervention study in 19 healthy volunteers, and an observational study in 26 surgical patients in VU University Medical Center, Amsterdam, the Netherlands.

Intervention

In healthy subjects, the intervention includes two fluid boluses (crystalloid and colloid) of 300 ml each.

Study burden and risks

Healthy subjects: healthy subjects will be exposed to an intravenous punction, two fluid boluses, 6 sublingual microcirculatory measurements and Nexfin hemodynamic measurements, which are all associated with minimal discomfort. Healthy subjects have no benefit from the present study.

Patients: Nexfin and microcirculatory measurements will be mostly performed during anesthesia, and the burden for the patient is minimal. Intraoperative fluid management is part of the standard anesthesia procedure. There are no benefits from the present study for the patient.

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

Healthy subjects
* Age 18-85 years
* Normal renal function
* Normal liver function
Patients
* Age 18-85 years
* Normal renal function
* Normal liver function

Exclusion criteria

Healthy subjects
* Peripheral edema
* Cardiovascular disease (hypertension, myocardial ischemia, heart failure)
* Use of antihypertensive, diuretics
* Allergy to gelatines
* Severe asthma;Patients
* Peripheral edema
* Myocardial infarction, heart failure, renal replacement therapy
* Use of diuretics
* Previous chemotherapy
* Diabetes mellitus I or II with use of anti-diabetic medication
* User of steroids

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2014
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Gelofusin
Generic name:	Gelatin
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Ringer's lactate
Generic name:	Ringer's lactate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	25-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2014
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
EudraCT	EUCTR2013-002044-81-NL
CCMO	NL44851.029.13