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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29320

Source
NTR

Brief title
CHALLENGE study

Health condition

microcirculation

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: VU University Medical Center

Intervention

Outcome measures

Primary outcome

Microcirculatory perfused vessel density (PVD) and perfused boundary region (PBR)

measured using sublingual Capiscope 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

This study will investigate the effects of a fluid challenge on microcirculatory vessel perfusion and the glycocalyx thickness.
It is hypothesized that infusion of crystalloid fluids in healthy subjects is associated with a volume-dependant reduction in microcirculatory perfused vessel density and an increase in perfused boundary region due to effects of cristalloid fluid loading.
Besides, an attenuation of cristalloid-induced alterations in microcirculatory perfused vessel density and perfused boundary region by colloid administration is hypothesized.

Study design

Healthy volunteers: 2 hours study period Patients: duration of anesthesia

Intervention

Healthy volunteers:

Subjects are first exposed to a bolus of crystalloid fluid (300 ml), which is followed by a bolus of colloid fluid (gelofusine) (300 ml).
Before and after fluid administration, the microcirculatory perfused vessel density and perfused boundary region are monitored using sublingual Capiscope imaging.
Subjects are hemodynamically monitored using Nexfin continuous blood pressure measurements.
The study ends after the last sublingual microcirculatory measurement.

Patients:
Anesthetized patients who are exposed to 500 ml crystalloid or colloid fluids (gelofusine) are monitored using sublingual Capiscope imaging to gain insight in the relation between the fluid balance and microcirculatory perfusion.
Before and after fluid administration, the microcirculatory perfused vessel density and perfused boundary region are monitored using sublingual Capiscope imaging.
Subjects are hemodynamically monitored using Nexfin continuous blood pressure measurements.
The study ends after the surgical procedure has been completed.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy volunteers (n=19): Age 18-85 years, normal renal function, normal liver function

Patients (n=26) undergoing elective abdominal surgery under general anesthesia, age 18-85

years, normal renal function, normal liver function

Exclusion criteria

Healthy volunteers:
Peripheral edema
Cardiovascular disease (hypertension, myocardial ischemia, heart failure)
Allergy to gelatines
Use of antihypertensive, diuretics
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
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	45
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL4315
NTR-old	NTR4468
Other	: ANES 2013/01

Study results