

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

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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...

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| Ethische beoordeling | Niet van toepassing |
| Status | Werving nog niet gestart |
| Type aandoening | - |
| Onderzoekstype | Interventie onderzoek |

Samenvatting

ID

NL-OMON29320

Bron

NTR

Verkorte titel

CHALLENGE study

Aandoening

microcirculation

Ondersteuning

Primaire sponsor: VU University Medical Center

Overige ondersteuning: VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Microcirculatory perfused vessel density (PWD) and perfused boundary region (PBR) measured using sublingual Capiscope imaging.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

DoeI van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Healthy volunteers:

Subjects are first exposed to a bolus of crystalloid fluid (300 ml), which is followed by a bolus of colloid fluid (gelfusine) (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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Niet-gerandomiseerd

Blinding: Open / niet geblindeerd

Controle: Geneesmiddel

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-04-2014

Aantal proefpersonen: 45

Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

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 | NL4315 |
| NTR-old | NTR4468 |
| Ander register | : ANES 2013/01 |

Resultaten