Global, regional and microvascular hemodynamics during fluid resuscitation following cardiac surgery, a pilot study.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46111

Source
ToetsingOnline

Brief title
The effect of fluid resuscitation on regional perfusion, a pilot study.

Condition

- Other condition

Synonym
1) Hemodynamic optimisation following CABG and/or heart valve replacement/repair. 2) Optimisation of blood flow after heart surgery.

Health condition

Hemodynamische instabiliteit

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: BBraun,Unristricted educational grant

Intervention

Keyword: Balanced fluids, Fluid resuscitation, Hemodynamics, Unbalanced fluids

Outcome measures

Primary outcome

Renal perfusion: δa.u./δCI

- δa.u. (arbitrary units) obtained by CEUS, expressed in percentages

- δCI (cardiac index) obtained by swan ganz, expressed in CO/m2 = (mL blood/minute)/m2

Hepatic perfusion: δPDR/δCI

- δPDR (plasma disappearance rate) obtained by LiMON, expressed in percentage/minute.

- Distribution and clearance of infused fluids by kinetic model analysis, estimating Vc, k10, k12, and k21 using hemoglobin sampling during and after infusion.

Secondary outcome

Not applicable.

Study description

Background summary

Recently studies have shown a beneficiary effect of using balanced fluid resuscitation unbalanced fluid resuscitation (the main difference being the chloride concentration) on the complications following kidney transplant, open abdominal surgery and help prevent AKI in ICU patients.
Animal test studies showed an overall better micro- and macro-vascular renal circulation.
The SPLIT Trials did not find an in-/decreased risk between the two different fluid resuscitation strategies. Further studies including specific ICU patient group were recommended.
In our pilot study we set out to investigate if balanced or unbalanced fluid strategies have a different effect on the renal and hepatic perfusion in patients following cardiac surgery. To investigate the difference in renal perfusion we will be using Contrast Enhanced UltraSound (CEUS). To assess the hepatic perfusion we will use indocyanine green and the LiMON system. The primary endpoint will be the change in cardiac index (CI) in association with the change in renal and hepatic perfusion. Each patient will serve as his/her own control by being administered unbalanced and balanced fluids. See protocol.

Study objective

The primary objective is to assess the effect a resuscitation strategy using balanced solutions versus unbalanced solutions on regional and microvascular perfusion relative to global hemodynamics in intensive care patients following elective cardiac surgery. See protocol.

Study design

Randomised controlled clinical crossover pilot study. See protocol.

Intervention

Administration of 2 x 250 mL routinely used balanced or unbalanced fluids. See protocol.

Study burden and risks

The use of the SonoVue contrast agent is associated with: headache, numbness, vertigo, dysosmia, flushing, sore throat, nausea, abdominal discomfort, itch, backache and hyperglycaemia (1:100 - 1:1000 patients); insomnia, pain or pressure in the ENT-region, blurred vision, hypotension, overall sensation of pain, pain on the chest, fatigue and allergic reactions ranging from erythema to anaphylaxis (1:1000-1:10.000 patients). The use of ICG is associated with rare cases of anaphylaxis. Especially in patients know with a iodine allery, iodine is a excipient in indocyanine green. See protocol.

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

Age > 18 years
ICU admission following elective cardiac surgery
Undergoing cardiac output monitoring with a Pulmonary Artery Catheter
Need for fluid resuscitation as determined by the treating intensivist

Exclusion criteria

Pregnancy
Renal failure (eGFR < 60ml/min/1.73 m2 or on RRT)
Iodide allergy

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2016
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Gelaspan 4%
Generic name:	not applicable
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Gelofusine 4%
Generic name:	not applicable
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	sodium chloride 0.9%
Generic name:	sodium chloride 0.9%
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sterofundin ISO

Generic name:	not applicable
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	02-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2017
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	EUCTR2016-000495-22-NL
CCMO	NL56705.029.16