Comparison of peripheral perfusion in central versus peripheral hypothermia induced peripheral vasoconstriction

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To observe the possible relationship between central, conventional hemodynamic parameters with relatively new peripheral, regional perfusion parameters in two versions of a model with controlled vasocontriction (cooling) - vasodilation (heating)

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

Summary

ID

NL-OMON34369

Source
ToetsingOnline

Brief title
Hypothermia and peripheral perfusion

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC

Synonym
hypothermia, peripheral perfusion

Health condition

hypothermie geïnduceerde patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Hypothermia, - Peripheral perfusion

Outcome measures

Primary outcome

To observe the effect of central and peripheral hypothermia induced by cooling,

on parameters of peripheral perfusion and central hemodynamic parameters.

Secondary outcome

- Evaluate the relationship between the different parameters of peripheral

perfusion during warming.

- Observe which interventions in the regular treatment (filling and inotropic)

effect parameters of the peripheral perfusion.

Study description

Background summary

Circulation of the body can be seen as consisting of a "central" and a "peripheral" compartment. The central (systemic) compartment, roughly includes the major blood vessels and is clearly ruled by cardiac function (stroke volume and contractility). It can be stated that the regulation of the central compartment, preferably serves the perfusion of the brain, which is the most vital organ.
The nature and regulation of the peripheral compartment are difficult to describe. First, non-vital organs (such as eg intestine and skin) can be considered as part of the peripheral compartment, on the other hand extremity (muscle, skin) are literally part of the peripheral circulation. Disruption of the circulation as a whole often leads especially to changes in the peripheral compartment. How the peripheral compartment behaves when heated, after vasoconstriction, in relation to central perfusion, cardiac function and

interventions is still unknown.

Study objective

To observe the possible relationship between central, conventional hemodynamic parameters with relatively new peripheral, regional perfusion parameters in two versions of a model with controlled vasocontriction (cooling) - vasodilation (heating)

Study design

This study is designed as a single-center observational study.

Study burden and risks

The microvascular peripheral perfusion is observed in all patients by Sidestream Dark Field imaging, NIRS, PFI, delta temperature and capillary refill time. This Sidestream Dark Field (SDF) imager is a new and more improved method to observe the sublingual microcirculation at bedside, see page 9-11 of the protocol for more explanation. All observations are not painful or invasive. By placing the camera at the mucosa under the tongue a good SDF-image can be made of the microvascular perfusion. Other parameters are assessed by different stickers on the skin or chest. Peripheral perfusion parameters are assessed one time only when the patient is warmed up at the ICU or CCU. SDF images are assessed during the heating process by every 0.5 degree warming. This represents no additional burden for the patient because the patient won*t notice anything due to the anesthesia of the. No additional lines have to be punctured.

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 volunteers:
o Age 18 years or older and mentally competent
o Informed consent of the volunteer.;Elective post-cardiac surgery population:
o Age 18 years or older and mentally competent
o Informed consent from the patient
o Patients listed for elective cardiac surgery surgery (CABG).;Post CPR population:
o Age 18 years or older.
o Informed consent from the patient or legal representative.
o Patients admitted to the CCU after CPR and are therefore 24 hours chilled.

Exclusion criteria

Healthy volunteers:
o Pregnancy
o Failure to monitor peripheral perfusion by any reason;Elective post-cardiac surgery population:
o Pregnancy
o Bleeding in the oral cavity or other circumstances that make adequate SDF shooting impossible
o Failure to monitor peripheral perfusion by any reason;Post CPR population:
o Bleeding in the oral cavity or other circumstances that make adequate SDF recordings impossible.
o Failure to monitor peripheral perfusion by any reason

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL32590.078.10