OPTIMIZING PERIPHERAL CIRCULATION WITH VASODILATOR THERAPY IN CRITICALLY ILL PATIENTS WITH CIRCULATORY SHOCK: A PILOT STUDY

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

Summary

ID

NL-OMON44686

Source
ToetsingOnline

Brief title
Vasodilator Therapy In Critically Ill Patients

Condition

- Other condition

Synonym
disease of circulatory system

Health condition

circulatory shock

Research involving

Human

Sponsors and support

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

Intervention

Keyword: capillary refill, critically ill, microcirculation, multiple organ failure, peripheral circulation, skin temperature, vasodilators

Outcome measures

Primary outcome

Capillary refill time (s), skin-difference temperature gradient (0C),

peripheral perfusion index (a.u.), resting peripheral tissue oxygenation (StO2)

values (%), rate of StO2 desaturation (%/min), rate of StO2 recovery (%/s),

sublingual microcirculation parameters [total vessel density (mm/mm2), perfused

vessel density (mm/mm2), and vessel diameters (µm), red blood cell velocity

(µm /sec), proportion of perfused vessels (%), microvascular flow index (a.u.),

and flow heterogeneity (a.u.)], gastric perfusion parameters (gastric mucosa

CO2 and EtCO2 difference).

Secondary outcome

Global hemodynamic parameters: Fluid balance, mean arterial pressure (MAP),

central venous pressure (CVP), central venous oxygen saturation (ScvO2),

cardiac output and stroke volume, blood lactate levels.

Respiratory function: arterial oxygen pressure/inspired oxygen fraction ratio

(PaO2/FiO2 ratio), mechanical ventilation free-days.

Other study parameters: length of ICU stay , Sequential organ failure

assessment score (SOFA), Acute Physiological and Chronic Health Evaluation

score (APACHE II).

Study description

Background summary

Recent clinical studies have shown a relationship between abnormalities in peripheral perfusion and unfavorable outcome in patients with circulatory shock. Nitroglycerin is effective in restoring alterations in microcirculatory blood flow. This study is aimed to investigate whether nitroglycerin could correct the parameters of an abnormal peripheral circulation in resuscitated circulatory shock patients.

Study objective

We hypothesize that stepwise dose of intravenous infusion of nitroglycerin reverses clinical abnormalities of peripheral circulation in patients with circulatory shock and that this can lead to improvement in survival rate. In addition, we expect that the easy and reliable clinical parameters of peripheral perfusion can be an effective monitoring approach at the bedside to titrate the beneficial effects of nitroglycerin on microcirculation in individual patient with circulatory shock during initial resuscitation.

Study design

The study is a pilot study and is designed as a randomized controlled trial, single-blinded. The study will be conducted as a single-center study at the Intensive Care of the Erasmus Medical Center.

Intervention

Patients will be treated according to their randomization group: nitroglycerin group or to standard (control) therapy. All patients will be treated according to the protocol for hemodynamic support without nitroglycerin (control group) or with nitroglycerin (intervention group). The nitroglycerin infusion rate will be maintained at 2ml/h (33,3 mcg/min), and patient will be reassessed each hour. In case of poor peripheral perfusion, nitroglycerin infusion rate will be increased in a stepwise dose until improvement in the peripheral perfusion parameters or a maximum dose of 16 mg/h is reached.

Study burden and risks

The suspected benefit is that survival rate in the treatment group can be

improved with nitroglycerin therapy guided by changes in peripheral perfusion parameters. There is no additional risk for patients concerning the measurements of peripheral perfusion as all the used techniques are noninvasive and harmless. There is a possible risk that in the treatment group the patients will have more chances to develop hypotension (MAP <65mmHg). To ensure that this will not occur, the vasopressor infusion (noradrenaline) will be started (in case the patient is not already receiving) or increased if MAP decreases <65mmHg, irrespective of peripheral perfusion parameters.

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

All consecutive adult patients admitted to the intensive care for circulatory shock resuscitation in whom abnormal peripheral perfusion is still present despite normalization of

global hemodynamic parameters are eligible for this study.

Exclusion criteria

Liver failure, severe coagulation disorder, and any neurological insult that could lead to increased intracranial pressure (stroke, subarachnoid haemorrhage, brain trauma injury).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	177
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	15-04-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-10-2017
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
EudraCT	EUCTR2013-002189-38-NL
CCMO	NL44945.078.13