Optimal cerebral perfusion after an extracranial-intracranial bypass: should we increase blood pressure or cardiac output?

Published: 06-06-2018
Last updated: 10-01-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON46670

Source
ToetsingOnline

Brief title
Optimization of cerebral perfusion after an EC-IC bypass

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovascular disease, vascular disease in the brain

Research involving
Human

Sponsors and support

Primary sponsor: Anesthesiologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood flow, Blood pressure (Mesh), Cardiac output (Mesh), cerebral (Mesh), EC-IC bypass

Outcome measures

Primary outcome

The mean change in graft flow rate (ml/min) during dobutamine administration to increase the cardiac output with 10% and the mean change in flow rate during administration of phenylephrine to increase the blood pressure with 10%.

Secondary outcome

Secondary endpoints are the difference in change in graft flow rate, cardiac output and blood pressure (compared to the reference stage) between the intervention to increase the cardiac output and the intervention to increase the blood pressure.

Study description

Background summary

In patients undergoing surgical cerebral revascularization with a bypass, the brain is at risk of ischemia. It is of great importance to maintain adequate cerebral tissue perfusion. Currently, emphasis is placed on blood pressure ranges to maintain tissue perfusion: high blood pressure levels are realized using vasopressors, but does this ensure adequate cerebral perfusion, since perfusion does not only depend on perfusion pressure but also on cardiac output? We hypothesize that cardiac output rather than blood pressure is essential for adequate cerebral perfusion during and after cerebral revascularization.

Study objective

We aim to study what the mean change in graft flow rate is when the cardiac

output is increased with 10% and what the mean change in graft flow rate is, when the blood pressure is increased with 10% to enable further research to establish whether an increase in cardiac output results in a higher graft perfusion than an increase in blood pressure in patients undergoing cerebral revascularization surgery with a bypass.

Study design

A randomized cross-over pilot study where patients randomly and sequentially receive dobutamine to increase cardiac output, and phenylephrine to increase blood pressure. Graft perfusion is measured with an ultrasonographic flow meter placed on top of the graft.

Intervention

Patients will receive, randomly and sequentially, dobutamine (2-15 µg/kg/min) to increase the cardiac output and phenylephrine (0.15-1 µg/kg/min) to increase the blood pressure.

Study burden and risks

The burden and risks of this study are negligible. This study will take place during the hemostasis phase of bypass surgery and does not significantly increase the length of the procedure and exposure to general anesthesia. Both phenylephrine and dobutamine are commonly and safely used in anesthetized and critically ill patients to maintain hemodynamic paramaters within a normal physiological range. Both drugs have a short duration of action and potential side-effects disappear within minutes after discontinuation. Routine hemodynamic monitoring, including 5-leads electrocardiogram and invasive blood pressure measurements will be used to titrate the dosage and to detect potential side-effects at an early stage. No further postoperative follow-up is required for this study. Although both drugs may increase the oxygen consumption of the myocardium, these effects are limited at the proposed dosages. Still, as a precaution, patients with a history of a recent myocardial infarction (<30 days), unstable angina, severe hyperthyroidism, severe, untreated, ventricular arrhythmia's, hypersensitivity to dobutamine or phenylephrine, hypertrophic cardiomyopathy and obstruction of the left ventricular outflow tract will be excluded. As an additional precaution, patients with a mean arterial blood pressure < 60 mmHg and/or a systolic blood pressure > 180 mmHg prior to start of one of the interventions will be excluded.

Contacts

Public
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adults, aged 18 years or above
Indication for extracranial-intracranial bypass surgery

Exclusion criteria

Patients within two weeks after a subarachnoid hemorrhage
Language barrier
Pregnancy
Hypertrophic cardiomyoapthy
Left ventricular outflow tract obstruction
Severe, untreated, ventricular arrhythmia

Severe hyperthyroidism
Recent myocardial infarction (<30 days) or unstable angina
Hypersensitivity to dobutamine or phenylephrine
Mean arterial blood pressure < 60 mmHg under general anesthesia before start of the study period
Systolic blood pressure > 180 mmHg under general anesthesia before start of the study period

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-09-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	06-06-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	08-06-2018
Application type:	First submission
Review commission:	METC NedMec

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	EUCTR2018-002008-15-NL
CCMO	NL65095.041.18

Study results

Date completed:	22-07-2019
Results posted:	14-07-2020

First publication
01-01-1900