How can we improve the blood flow to the brain during the construction of a bypass in the brain?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23040

Source
NTR

Health condition

Indicatie for an extracranial-intracranial bypass: either flow augmentation for patients with steno-occlusive vascular disease such as moyamoya disease or flow preservation when a major artery has to be sacrificed to treat an underlying disease such as a tumor of the central skull base or a complex intracranial aneurysm.

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

First, we will measure the graft flow rate to be used as a reference for graft perfusion. Afterwards the cardiac output or blood pressure is increased. Our main study parameter will be the mean (sd) change in graft flow for an increase in cardiac output compared to the

reference phase and the mean (sd) change in graft flow for an increase in blood pressure, compared to the reference phase.

Secondary outcome

Secondary endpoints are the absolute difference in increase (or decrease) in graft flow rate, cardiac output and blood pressure between dobutamine and phenylephrine treatment, as compared to the reference stage.

Study description

Background summary

Patients receiving cerebral revascularization with a bypass are prone for cerebral hypoperfusion. Currently, blood pressure is often increased with vasopressors to prevent cerebral ischemia. However, this might cause vasoconstriction of the graft and cerebral vasculature. We hypothesized that cardiac output rather than blood pressure is essential for adequate cerebral perfusion and aimed to determine whether an increase in cardiac output results in higher graft perfusion (and thus cerebral perfusion) than an increase in blood pressure in patients undergoing cerebral bypass surgery. This randomized crossover monocenter study included 10 adult patients undergoing cerebral bypass surgery. Patients randomly and sequentially received dobutamine to increase the cardiac output (indexed for body surface area) and phenylephrine to increase the mean arterial blood pressure (MAP). An increase of >10% in cardiac index and >10% in MAP was targeted, respectively.

Study objective

We hypothesize that cardiac output rather than blood pressure is essential for adequate cerebral perfusion during and after cerebral revascularization.

Study design

All interventions and measurements will be done during the hemostasis phase of extracranial-intracranial bypass surgery

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Patients within two weeks after a subarachnoid hemorrhage

Language barrier

Pregnancy

Hypertrophic cardiomyopathy

Left ventricular outflow tract obstruction

Severe, untreated ventricular arrhytmia

Severe hyperthyroidism

Recent myocardial infarction (<30days) 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:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2018
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-06-2018
Application type:	First submission

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
NTR-new	NL7077
NTR-old	NTR7275
Other	METC UMC Utrecht : 18-321/G-M

Study results

Summary results
none