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

Gepubliceerd: 15-06-2018 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23040

Bron
NTR

Aandoening

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.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

UMC Utrecht, dep. of Anesthesiology

A. Akkermans
Heidelberglaan 100

Utrecht 3508 GA
The Netherlands
+31887577081

Wetenschappelijk

UMC Utrecht, dep. of Anesthesiology

A. Akkermans
Heidelberglaan 100

Utrecht 3508 GA
The Netherlands
+31887577081

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7077
NTR-old	NTR7275
Ander register	METC UMC Utrecht : 18-321/G-M

Resultaten

Samenvatting resultaten
none