Assessing brain hemodynamics using Arterial Spin Labeling MRI.

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Ethical review	Not approved
Status	Will not start
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON35194

Source
ToetsingOnline

Brief title
A-CO2

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cerebrovascular disease, stroke

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial Spin Labeling, Cerebral Metabolic Rate of Oxygen, Cerebrovascular Reactivity, Respiratory challenge

Outcome measures

Primary outcome

Our objective is to test the feasibility of the application of a CO2-challenge

to measure Cerebrovascular Reactivity in healthy subjects and in

cerebrovascular diseased patients with Arterial Spin Labeling MRI and to test

the feasibility of a Velocity-Selective Spin Labeling sequence to measure the

Cerebral Metabolic Rate of Oxygen.

Secondary outcome

To obtain baseline values of these two parameters in a healthy control group

and in patients with cerebrovascular disease.

Study description

Background summary

In vascular brain diseases vasodilatation of the vessels and increased oxygen extraction are important to maintain homeostasis and are correlated with the severity of the disease. In order to obtain full knowledge about brain tissue hemodynamics it is important to obtain a measurement of these two parameters.

Study objective

With this study we want to measure the two parameters who determine the hemodynamic status of the brain tissue. The first parameter we want to determine is the Cerebrovascular Reactivity (CVR), which is a measure for the degree in which blood vessels can dilate. The second parameter is the Cerebral Metabolic Rate of Oxygen (CMRO2), which is a reflection of the oxygen-use in brain tissue.

Study design

To measure the Cerebrovascular Reactivity we will use a respiratory challenge (RespirAct TM), this because it is well known that an increase in arterial blood gas CO2 within physiological values causes dilatation of the brain vessels. This dilatation is reflected in an increase in brain perfusion. Arterial Spin Labeling (ASL) Magnetic Resonance Imaging (MRI) will be used to evaluate this increase in brain perfusion. Furthermore we will apply a Velocity Selective Spin Labeling MRI sequence which selectively labels the blood in the venous compartment and permits us to assess oxygen-use (CMRO2) in brain tissue.

Intervention

All volunteers and patients will be exposed to step wise respiratory challenges with a maximum of 4 minutes of end tidal CO2 pressure (= arterial pressure) of 50 mmHg CO2 and minimum O2 level of 100 mmHg (= normal end-tidal arterial O2 pressure). These CO2 and O2 levels are within physiological ranges.

Study burden and risks

The controlled gas breathing requires a closed breathing system. Therefore, subjects have to breath through a mask, which might be a bit uncomfortable. CO2 end-tidal levels of 50 mmHg can induce an increased breathing frequency due to physiological stress. However, end-tidal levels of 50 mmHg CO2 is within the physiological range and is experienced repeatedly by most people over the day (eg. during exercises). If patients experience discomfort they can open a valve in the mask or we can smitch immediately to 100% oxygen by pushing the red button on the front of the gas blender. Volunteers and patients can also always squeeze the panic button in the MRI. Risks associated with controlled gas breathing of high levels of CO2 are minimized because the minimum O2 level in the gasses is 10%. Breathing frequency, CO2- and O2-levels are continuously digitally analysed and monitored by the RespirAct TM device. An independent blood oxygen saturation monitoring will be performed during the MRI measurements with fingertip pulse oxymetry.

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

(p. 15 protocol)
> 18 year
informed consent
Intracranial occlusion
Extracranial occlusion
Extracranial stenosis
In stroke patients, MRI scan within one week of symptom onset

Exclusion criteria

(p.15 protocol)
Contraindications for MRI (claustrophobia, or standard MRI contraindications such as pacemakers or specific metal objects in or around the body)
Unwilling or unable to co-operate with breathing manoeuvres
Respiratory or cardiac limitations to breathing at 20L/min
Medical contra-indications to limited hypercapnia (known increased intracerebral pressure, metabolic acidosis or alkalosis)
Altered consciousness
Non compliance with prescribed anti-seizure medication

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	160
Type:	Anticipated

Ethics review

Not approved

Date:	09-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL38380.041.11