Non-invasive mapping of the Cerebrovascular Reactivity with ASL, BOLD and VASO MRI using different stimuli in young and elderly healthy volunteers

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON39116

Source
ToetsingOnline

Brief title
CVR measurements with MRI

Condition

- Central nervous system vascular disorders

Synonym
Microvascular pathologies of the brain, Vascular diseases of the brain

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ASL, Cerebrovascular reactivity, functional MRI, Stimulation paradigms

Outcome measures

Primary outcome

Cerebral Blood Flow (CBF=ml blood/100 ml brain tissue/minute), relative

Cerebral Blood Volume (rCBV=ml blood/100 ml brain tissue) and Blood Oxygenation

Level Dependent (BOLD=%). MCA diameter (mm)

Secondary outcome

None.

Study description

Background summary

A normally working cerebral hemodynamics is of vital importance for a proper functioning of the human brain. An altered vascular reserve capacity and failure of the vascular autoregulation of the brain is thought to be the cause or a first manifestation of many cerebrovascular diseases. The Cerebrovascular Reactivity (CVR) is a measure of the vascular reserve capacity of the brain. For instance, it has been shown that Cerebrovascular Reactivity measurements can be of prognostic value in the cerebrovascular pathologies like CADASIL. In order to assess the value of CVR as a diagnostic/prognostic tool, first a rigorous characterization of the measurement procedure should be performed. Depending on its definition, CVR can be measured as the change in Cerebral Blood Flow (CBF), Cerebral Blood Volume (CBV) or blood oxygen content following the delivery of a stimulus. There are several MRI techniques frequently used in clinic and research for the measurement of these hemodynamic parameters, namely ASL, VASO and T2*-weighted imaging (BOLD) for the measurement of CBF, CBV and blood oxygenation, respectively.
When measuring CVR using these techniques (ASL, BOLD and VASO MRI) a challenge is needed to provoke a vascular response. There are several paradigms available

for this purpose, including hypercapnia, hypoxemia, breath holding, administration of pharmacologically active substances (e.g. acetazolamide), and neuronal activation. The latter can be achieved by carrying out a simple task, e.g. finger tapping, or visual stimulation.
In summary, there are different possibilities to measure CVR using a combination of one of the several MRI techniques and stimulus paradigms. Currently it is unknown how the choice of a particular combination of technique and vascular challenge affects the detectability of vascular changes. It is therefore important to investigate the possible effects of this choice on the measurement of CVR in young subjects versus elderly subjects and establish a measurement protocol that can be applied in both clinical and research settings.

Study objective

The goal of this study is to perform an analysis of the ability of the different combinations of MRI technique/stimulation delivery to measure the cerebrovascular reactivity. In this study only the following stimulations will be used for the activation of the intracerebral vasculature: neuronal activation (visual stimulation), hypercapnia and hypoxia.
In the third part of this study, we will try to map the cerebrovascular reactivity curve of CO2 in young healthy adults, while simultaneously correcting for mean arterial blood pressure changes due to CO2.
In the last part we will study the middle cerebral artery (MCA) diameter changes due to changes in arterial CO2 levels.

Study design

This study is divided into two parts. In the first stage 10 subjects will be scanned to optimize the scan protocols for the different MRI scan techniques. In the second part 15 young and 15 elderly subjects will be scanned with three different MRI scan techniques (ASL, BOLD and VASO) while consecutively exposed to three different stimuli (visual stimulation (neuronal activation), hypercapnia and hypoxia). The CVR measurements acquired with different techniques and under different conditions will be compared and also a comparison of the results for the different age groups will be done.
Addendum: The third objective of this study is to map the CO2 cerebrovascular reactivity with CBF measurements with arterial spin labeling MRI.
Addendum II: The fourth objective of this study is to assess weather the MCA vessel diameter changes due to changes in blood CO2.

Study burden and risks

The risks for the participants are, as for standard MR scans, negligible. The only matter of concern is the induction of blood gas changes which might pose a risk for some subjects, especially the elderly. But because the subjects are

healthy and the induced gas changes are relatively small the risk is also small. Furthermore in the past our research groups at LUMC have successfully performed other studies in which similar gas changes were induced and thus have the appropriate knowledge to perform these experiments.

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

1. Healthy volunteers (males of females) from the age groups of 18-35 years (25+15 (Addendum)) and 60-75 years (15 volunteers)
2. Volunteer participation
3. Having given their written informed consent
4. Willing to comply with the study procedures
5. Willing to accept use of all anonymized data, including publication, and confidential use

and storage of all data

Exclusion criteria

1. Smoking or having stopped smoking shorter than 10 years ago
2. Having cardiovascular disease (inc. diabetes and hypertension)
3. Having brain disease
4. Using drugs
5. having metal implants
6. Claustrophobic or other mental and physical status that is incompatible with the proper study conduct
7. Not having a General Practitioner.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2011
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	14-12-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	21-12-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	10-04-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL33107.058.10

Study results

Date completed:	01-12-2016
Actual enrolment:	40