Evaluation of distribution differences in cerebral blood flow with pseudo-continuous arterial spin tagging

Published: 31-10-2007
Last updated: 08-05-2024

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

Summary

ID

NL-OMON31079

Source
ToetsingOnline

Brief title
ASL

Condition

- Central nervous system vascular disorders

Synonym
Cerebral perfusion deficits

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: Arterial spin labeling, Magnetic resonance imaging, Perfusion

Outcome measures

Primary outcome

Identification how accurate and precise arterial spin tagging MRI can

identifies local perfusion deficits.

Secondary outcome

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Study description

Background summary

In patients with brain disease altered distribution of blood flow is observed. For example, it was observed in patients with Alzheimer disease that decreases in cortical blood flow are correlated with dementia severity and that the blood flow distribution is more heterogeneous. Also for cerebral vascular accidents it has been shown that changes in cerebral blood flow predict occurrence of ischaemia. However, because of the invasive nature of all commonly used perfusion techniques, large population based studies of the pattern of blood flow distribution are scarce. However, the recently developed technique of arterial spin tagging MRI (magnetic resonance imaging) offers a fast, high resolution, accurate and complete non-invasive technique of perfusion imaging . However, until now it has not been shown how accurate and precise arterial spin tagging MRI is able to identify such differences in blood flow distribution.

Study objective

The goal of this study is to investigate how accurate and precise arterial spin tagging MRI can be used to identify differences in blood flow distribution between different subject groups. Such local perfusion differences are modelled in normal healthy volunteers by either activating the visual or motor cortex or by scanning the volunteer in rest conditions.

Study design

Thirty volunteers will be scanned for approximately 30 minutes, encompassing a

total of 8 scans. The first 4 scans are basic anatomy and scout images. The final four scans are ASL perfusion scans, during which the volunteer watches a fixation cross, watches cartoons (weak visual stimulus), watches a 8 Hz inverting dartboard, or is performing a motor task (fingertapping). Volunteer will receive ear-protection and head-phones for communication purposes. Total duration of examination will be 60 minutes including waiting time and reading/signing of forms.

Study burden and risks

No side effects of MRI have been proven and MRI is generally assumed to be completely safe. The volunteer is protected against scanner noise. The examination takes at maximum only 45 minutes and the volunteerd can withdraw at any time during the study. Finally, subjects are screened for claustrofobia.

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 male or female subjects with age >18 and < 35 year
2. Voluntary 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 the confidential use and storage of all data

Exclusion criteria

1. Having a history of or current brain or vascular disease (including diabetes)
2. Claustrophobia
3. Having metal implants (i.e. pacemaker, metal joints, prostheses, etc.) or metal objects on the body which cannot be removed (i.e. piercing, hearing aid, brace, etc.)
4. Mental or physical status that is incompatible with the proper conduct of the study
5. Not having a general practitioner
6. Being under medication

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL17240.058.07