Quantitative ASL test-retest study

Published: 14-08-2007
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The purpose of this study is to assess the reproducibility of ASL perfusion measurement in the brain.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON31112

Source
ToetsingOnline

Brief title
ASL test-retest study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Carotis occlusion and stenosis.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial spin labeling, cerebral blood flow, MRI

Outcome measures

Primary outcome

Cerebral blood flow (100 ml/min/100gr)

Secondary outcome

none

Study description

Background summary

The purpose of this study is to assess the reproducibility of ASL perfusion measurement in the brain. ASL is attractive for especially longitudinal studies of cerebral blood flow, partly because ASL is an entirely non-invasive technique that does not involve exposure to ionizing radiation or radioactive isotopes. However, in order to plan such studies, whether as a single center or multicenter trial, the error of the measurement itself as well as the natural fluctuations of cerebral blood flow (CBF) needs to be taken into account when planning patient population size for a give study.

Study objective

The purpose of this study is to assess the reproducibility of ASL perfusion measurement in the brain.

Study design

Multicenter trial. A total of 10 volunteers will be scanned each two times , at a minimum of 1 week interval and maximum of one month to measure brain perfusion. A total of 30 sites will participate in this multicenter trial, producing a total of 300 subjects.

Study burden and risks

There are no risks. The burden consists of two times a MRI scan (30 minutes). Furthermore, no medication, beverage or food with vaso-dilatory or vaso-constrictive effects should be taken before the study (< 24 hours).

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

- 18 years or older

Exclusion criteria

- Impossibility to undergo MRI (claustrophobia, metal objects in or around the body).
- Within 24 hours of MRI scan the use of medication, beverages or food with vaso-dilatory or vaso-constrictive effects

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2007
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2007
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	NL18591.041.07