The VESPA study: Vendor-specific features of clinical ASL-MRI

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37480

Source
ToetsingOnline

Brief title
VESPA

Condition

- Other condition

Synonym
Er wordt geen aandoening bestudeerd.

Health condition

Geen aandoening

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial spin labeling (ASL), non-invasive MRI, reproducibility, two vendors

Outcome measures

Primary outcome

CBF (mL per 100 grams of brain tissue per minute) as assessed by ASL at 3.0 T

MRI

Secondary outcome

NA

Study description

Background summary

Arterial spin labeling (ASL) is a non-invasive magnetic resonance imaging (MRI) technique for the quantification of perfusion. From all MRI perfusion modalities, it is the only one that is harmless, not hampered by blood-brain barrier breakdown and acquires absolute quantification of perfusion. Reproducibility of ASL CBF measurements remains an important concern when using ASL in clinical routine. Until now, reproducibility studies have focused on single center and single vendor designs and did not compare results obtained from scanners of different vendors. (2-5,16,18). When using ASL in clinical practice, knowledge of the variability in and between scanning sessions and variability between MR scanners is of utmost importance to correctly interpret perfusion changes over time. Moreover, it is important to take inter-vendor (or inter-center) reproducibility into account in the definition of reference values for CBF.

Study objective

Therefore, the aim of this study will be to assess reproducibility of pseudo-CASL (p-CASL) between 3.0 Tesla MR scanners of two vendors in two

medical centers.

Study design

To assess the reproducibility, the inter-vendor reproducibility will be compared to the intra-vendor reproducibility. To assess the intra-vendor reproducibility of p-CASL, we will perform p-CASL measurements in two distinct MRI-examinations in each center. To study the inter-vendor (or inter-center) reproducibility of p-CASL, we will compare CBF at the two locations.

Intervention

200 mg. cafeine per scan

Study burden and risks

This study is conducted using a non-invasive imaging modality: MRI. MRI is considered harmless. Participants will be extensively screened for contraindications by an experienced researcher upon inclusion in the study. All scans are reviewed for incidental findings by a Neuroradiologist (dr. M. Smits). If clinically relevant abnormalities on the MR images are apparent, the volunteer is informed and a specialist will be consulted. The consumption of 200 mg of caffeine is comparable to the amount of caffeine ingested when drinking 2 cups of coffee. Health risks associated with consuming 200 mg of caffeine are highly unlikely in healthy volunteers, but possible side effects of 200-250 mg may include insomnia, agitation, nervousness, mild delirium and bradycardia.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• healthy adult volunteers, between 18 to 40 years of age
• non-smoking
• informed consent

Exclusion criteria

• inability of the patient to provide informed consent or legally incompetent/incapacitated to do so
• presence of metal in the body (e.g. osteosynthetic material, pacemaker, artificial cardiac valves)
• claustrophobia
• history of brain surgery
• history of brain or psychiatric disease
• use of medication with the exception of oral contraceptives.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-07-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL39853.078.12