Healthy volunteer study for development of ASL MR for perfusion imaging of salivary glands

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Primary: to determine normal values and test-retest variation of salivary gland perfusion using ASL in healthy volunteers. Secondary: to test the procedure by measuring possible perfusion differences during stimulated or suppressed salivation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Endocrine and glandular disorders NEC
Study type	Interventional

Summary

ID

NL-OMON46769

Source
ToetsingOnline

Brief title
Volunteers ASL MR salivary glands

Condition

- Endocrine and glandular disorders NEC

Synonym
Normal perfusion and adaptation thereof to stimuli of the salivary glands.

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ASL MR, perfusion, Salivary glands

Outcome measures

Primary outcome

The semi-quantitative perfusion signal will be measured on ASL MR maps from representative slices of the parotid and submandibular glands. Perfusion will be expressed in mL/min/100g tissue. This will be used to calculate the normal value (median) with confidence interval per gland type. The variation between separate scans will be used to calculate the intra- and inter-day variation.

Secondary outcome

The detectability of effects will be estimated based on comparison of baseline scans with intervention scans (stimulation or suppression of salivation).

Study description

Background summary

Salivary toxicity may be induced by several treatment modalities, and can lead to a dry mouth with severe impact on quality of life. Reducing the perfusion of salivary glands can potentially lower toxicity from many pharmaceuticals. To test such interventions a non-invasive and non-toxic instrument is needed to evaluate local perfusion. ASL MR is a commercially available method to measure perfusion of tissues, without intravenous contrast and with CE-mark. The application for evaluation of perfusion in salivary glands is new, and therefore normal values and test-retest values are currently unknown.

Study objective

Primary: to determine normal values and test-retest variation of salivary gland perfusion using ASL in healthy volunteers. Secondary: to test the procedure by measuring possible perfusion differences during stimulated or suppressed salivation.

Study design

On day 1, volunteers will receive two baseline MRI scans with ASL sequence within a few hours (intra-day test-retest variation). On day 2, volunteers will receive one baseline MRI scan with ASL sequence (multi-day test-retest variation), and one with either stimulation or suppression (effect evaluation).

Intervention

The first 3 scans have no intervention. De last scan will be acquired during stimulation or suppression of salivation (random). Stimulation of salivation is achieved by citric acid, smelling food or thinking of food. Suppression of salivation is achieved by cooling of salivary glands with household cooling packs.

Study burden and risks

Four ASL MRI scans will be acquired, divided over 2 days. One scan takes max 30 minutes. There are no significant risks for well-screened healthy volunteers.

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

Healthy volunteer.

Exclusion criteria

Age <18.
Inability to provide informed consent.
History of disease of the salivary glands.
Contra-indications for MR.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO Date:	12-06-2018
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL65464.031.18