

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

Published: 12-06-2018

Last updated: 11-04-2024

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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Endocrine and glandular disorders NEC
<b>Study type</b>	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. The 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

### Public

Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121  
Amsterdam 1066 CX  
NL

### Scientific

Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121  
Amsterdam 1066 CX  
NL

## 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