

# Endoscopic treatment of salivary glands affected by Sjögren Syndrome; A pilot study

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The focus of this pilot study is to investigate the results of a sialendoscopy (with or without rinsing with hydrocortisone 100mg) on the unstimulated whole mouth (UWS) and stimulated parotid (SP) (ml/min) flow of saliva, oral dryness, reported...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40344

### Source

ToetsingOnline

### Brief title

Endoscopic treatment of salivary glands affected by Sjögren Syndrome

### Condition

- Autoimmune disorders

### Synonym

Dry mouth disease, Sjögren Syndrome

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Dry Mouth, Salivary glands, Sialendoscopy, Sjögren Syndrome

## Outcome measures

### Primary outcome

The main study parameter is the change in unstimulated whole mouth and stimulated parotid salivary flow in ml/min after sialendoscopic treatment, with or without rinsing with hydrocortisone, compared to baseline and compared to a non-treatment control group.

### Secondary outcome

The secondary parameters are the mouthfeel score (XI score), the ESSPRI and the CORDIS score

## Study description

### Background summary

Sjögren's syndrome (SS) is an autoimmune inflammatory disorder of the exocrine glands. It particularly affects the lacrimal and salivary glands. Severe dry mouth and eyes are frequently reported as presenting symptoms. These symptoms are in many cases accompanied by nonspecific symptoms, such as malaise and fatigue. In addition, extraglandular manifestations, like purpura, polyneuropathy, and arthritis, can be present. SS affects mainly women with a female/male ratio of 9:1 and can occur at all ages. Due to the irreversible damage to the saliva producing cells, the quantity and quality of saliva reduces. The progressive nature of the syndrome results in a further reduction of salivary flow. Due to hyposalivation the patients suffer from progressive dental decay, dental erosion, severe drymouth complaints (i.e. eating and swallowing problems, lack of taste), inflammation of the oral mucosa and lack of retention of removable dentures. Overall, this can be qualified as a drop in the quality of life. Until now no effective palliative therapy to relieve dry mouth complaints is available. A recent case series study suggests that an endoscopic technique (sialendoscopy) is able to alleviate the symptoms of patients suffering from SS. In this technique the ducts of the salivary glands are rinsed with saline and cortisone and possible strictures are dilated. It is

hypothesised that performing a sialendoscopic treatment will raise or restore (un)stimulated salivary flow levels and enhance the reported mouthfeel score.

## **Study objective**

The focus of this pilot study is to investigate the results of a sialendoscopy (with or without rinsing with hydrocortisone 100mg) on the unstimulated whole mouth (UWS) and stimulated parotid (SP) (ml/min) flow of saliva, oral dryness, reported mouthfeel and clinical SS symptoms of diagnosed Sjogren\*s Syndrome patients. Also the long-term effects of sialendoscopy on the salivary flow, oral dryness and subjective changes in mouthfeel are measured.

## **Study design**

RCT, blinded

## **Intervention**

in every participating volunteer a sialendoscopy of the parotid glands and submandibular glands is performed.

## **Study burden and risks**

Sialendoscopy is a minimal invasive technique, which is a clinically accepted in the Netherlands to treat obstructive salivary gland diseases. Sialendoscopy is performed under general anaesthesia. The burden for participating volunteers is a consultation visit followed by a 1 day admission on which the intervention is performed. A reported side effect is post-operative swelling. One week after the intervention the follow-up schedule is started. In every visit (except the intervention visit) the patient has to donate saliva by spitting in a cup and has to fill out questionnaires. With these questionnaires the change in subjective oral dryness and mouthfeel is recorded. The benefit for the participating volunteer is a possible reduction of dry-mouth complaints and (partial) restoration of salivary flow.

## **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

- A diagnosed Syndrome of Sjögren (Eular guidelines)
- A remaining salivary flow
- Age > 18 years and < 70 years

### Exclusion criteria

- A complete lack of measurable salivary flow, also after stimulation of the glands by taste or chewing
- Acute sialadenitis
- Use of sialogogue medication (i.e. pilocarpine or cevimeline)
- Other severe illnesses or physical conditions that make a treatment under general anesthesia impossible or highly riskful

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2014
Enrollment:	60
Type:	Actual

## Medical products/devices used

Generic name:	Sialendoscopy
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	17-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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

CCMO

### ID

NL44018.029.13