Intervention study of oral dryness - Armor.

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The current study is aimed to evaluate the effect of a novel mouthwash on the relieve of a dry mouth sensation in Sjögren syndrome patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40736

Source
ToetsingOnline

Brief title
Isoda

Condition

- Other condition

Synonym
dry mouth sensation, xerostomia

Health condition

xerostomie

Research involving
Human

Sponsors and support

Primary sponsor: VU Medical Centre
Source(s) of monetary or material Support: Amor Proteines

Intervention

Keyword: mouthwash, Sjögren, xerostomia

Outcome measures

Primary outcome

The main study parameter is dry mouth sensation, assessed with the validated

Visual Analogue Scale questionnaire and the Xerostomia Inventory.

Secondary outcome

The secondary objective of this study is to evaluate the overall appreciation

of the mouthwash.

Study description

Background summary

Saliva has an important function in digestion, speech, and maintenance of oral health. Xerostomia is the subjective feeling of oral dryness, which is often (but not always) associated with hypofunction of the salivary glands. A deficiency to produce saliva can be caused by autoimmune disorders (including Sjögren syndrome), radiotherapy of head and neck, as a side effect of medication and dehydration. Prolonged periods of xerostomia can hinder chewing, swallowing and speaking and increase the risk for tooth decay. Xerostomia patients often experience a significant decreased quality of life. With the increase in xerostomia in population, there is an urgent need for solutions that stimulate, complement or replace the salivary functions.

Study objective

The current study is aimed to evaluate the effect of a novel mouthwash on the relieve of a dry mouth sensation in Sjögren syndrome patients.

Study design

The study is designed as a randomized parallel placebo-controlled double blind study.

Intervention

During the intervention a random selection of half of the group of Sjögren patients will be requested to rinse two times a daily with 15 ml mouthwash for one minute . The other half of the group of patients will receive a placebo, and be requested to use it in the same manner as the actual product. This duration of the trial is 14 days.

Study burden and risks

We anticipate that the burden and risk of participating in this study is low. At the salivary clinic an assessment of the dryness of the mouth will be performed, according to normal clinical practice. After this, the volunteers that are included in the study will use a mouthwash or rinse with a placebo in a non-invasive manner, and it is expected that this will relieve their symptoms of in case of the placebo, have no effect at all. The mouthwash is tested to be safe and to have no adverse effects.

Contacts

Public
VU Medical Centre

De Boelelaan 1117
Amsterdam 1081 HZ
NL
Scientific
VU Medical Centre

De Boelelaan 1117
Amsterdam 1081 HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Sjögren syndrome patient * diagnosed and / or self-reported
- Reported complaints of dry mouth
- Unstimulated salivary flow <0.20 ml/min

Exclusion criteria

- Medication affecting taste or salivary flow
- Head and neck radiated therapies
- Unstimulated salivary flow > 0.20 ml/min
- No computer / e-mail / not familiar or capable using the online web site

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2014
Enrollment:	66
Type:	Actual

Medical products/devices used

Generic name:	Armor-1
Registration:	No

Ethics review

Approved WMO Date:	11-11-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL50616.028.14