INTERVENTION STUDY FOR THE RELIEF OF ORAL DRYNESS – NOVOSPRAY

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20248

Source
NTR

Brief title
NOVOSPRAY

Health condition

Patients with Sjögren’s syndrome, suffering from a dry mouth sensation (xerostomia)

Sponsors and support

Primary sponsor: Academic Centre for Dentistry Amsterdam (ACTA)
Source(s) of monetary or material Support: Newtricious R&D

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the effect of an artificial saliva substitute on the sensation of a dry mouth.
This will be measured according to a VAS questionnaire for subjective assessment of salivary dysfunction.

In addition, the Xerostomia Inventory will be used to quantify the severity of oral dryness.

Secondary outcome

A secondary objective of this study is to evaluate the overall appreciation of the saliva substitute. This objective will be assessed by a product appraisal questionnaire. Another secondary objective is to evaluate effects of the artificial saliva on the saliva secretion rate.

Study description

Background summary

Rationale: 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 affect the global oral comfort (dryness, burning) and 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 relieve dry month symptoms effectively.
Objective: To evaluate the effect of a newly developed artificial saliva spray on the relief of a dry mouth sensation in Sjögren syndrome patients
Study design: The study is designed as a randomized cross-over placebo-controlled double blind intervention study
Study population: 30 patients diagnosed with Sjögren syndrome, with complaints of xerostomia and hyposalivation, age over 18 years
Intervention: The Sjögren patients will be requested to use the actual product and the placebo both for two weeks according to their needs, The patients will receive the actual product and the placebo in random order, resulting in a total duration of the experiment of four weeks.
Main study parameters/endpoints: The main study parameter is dry mouth sensation, assessed with the validated Visual Analogue Scale questionnaire and the Xerostomia Inventory.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We anticipate that the burden and risk of participating in this study is low. At intake the dryness of the mouth will be assessed, according to normal clinical practice. After this, the volunteers that are included in the study will use an artificial saliva spray and a placebo, and it is expected that the test product will relieve their symptoms more efficiently than the placebo product. The artificial saliva spray contains an ingredient derived from chicken eggs. Subjects with an allergy for products derived from chicken eggs will be excluded.

Study objective

A newly developed artificial saliva spray (Novospray) alleviates the feeling of a dry mouth in patients suffering from
xerostomia better than placebo.

Study design

data are collected at day 0, 7 and 14 of the two weeks period when the artificial saliva spray is used, and at day 0, 7 and 14 of the two weeks period when the placebo is used

Intervention

two week use of an artifical saliva spray and two weeks use of a placebo, in random order

Contacts

Public
Academic Centre for Dentistry Amsterdam (ACTA)
Henk Brand

+31205980897
Scientific
Academic Centre for Dentistry Amsterdam (ACTA)
Henk Brand

+31205980897

Eligibility criteria

Inclusion criteria

• Male or female, over 18 years of age, and capable of providing their written informed consent.
• An unstimulated whole mouth salivary flow < 0.20 ml/min [8].
• Demonstrated moderate to severe level of dry mouth at screening, as indicated by an XI-score of 25 or higher
• Diagnosis of Sjögren's syndrome.
• Access to internet.

Exclusion criteria

• Patients currently using a potassium-sparing diuretic antihypertensive drug that contains amiloride; spironolactone (e.g.,Aldactone, Novo-Spiroton, Spiractin, Spirtone, Verospiron or Berlactone); triamterene (e.g., Dyrenium); or plerenone (e.g., Inspra). Chronic use of antihistamines will be permitted if started at least 30 days before the start of the trial, and a stable dose is maintained throughout the trial.
• Patients who started using systemic cholinergic secretagogues or tricyclic antidepressant drugs within 12 weeks before screening, patients who are not on a stable dosing regimen for at least 14 days prior to the screening visit, or patients who are unable to maintain stable dosing throughout the study.
• Females who are pregnant or trying to become pregnant, or are nursing.
• Patients showing evidence of a significant active or ongoing oral infection or other oral conditions (eg, lichen planus) that, in the opinion of the Investigator, might affect the safety of the subject or be exacerbated during study participation.
• Patients suffering from acute infections of the salivary glands.
• Patients with a present history of any clinically significant and uncontrolled neurologic, gastrointestinal, renal, hepatic, cardiovascular, psychological, pulmonary, metabolic, endocrine, or hematological disorder or disease, or any other major disorder or disease, in the opinion of the Investigator.
• Patients consuming more than 2 alcoholic drinks per day or with a significant history of alcoholism or drug/chemical abuse within the past 12 months.
• Patients who have received an investigational drug within the past 30 days.
• Patients with a history of allergy to chicken egg proteins or food preservatives
• Patients having an unstimulated whole mouth salivary flow > 0.20 ml/min.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-10-2019
Enrollment:	35
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	31-07-2019
Application type:	First submission

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
NTR-new	NL7930
Other	METC Vumc : 2018.681

Study results