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Effects of gustatory stimulants of salivary secretion on the pH and stimulation of saliva of Sjögrens syndrome patients

Submission date 03/01/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/03/2010	**Overall study status** Completed	
Last Edited 16/03/2010	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of gustatory stimulants of salivary secretion on the pH and stimulation of saliva of Sjögrens syndrome patients: a two arm parallel single centre randomised controlled trial

Study objectives
Gustatory stimulants of salivary secretion (GSSS) are sold over the counter in wide number of European countries and used to stimulate salivary secretion. The acidic nature of these lozenges suggests that they may increase the risk for dental erosion.

The rationale for this study being to find out if the use of the Dentaid GSSS increases salivary secretion and is safer regarding dental erosion.

The study hypotheses are:
1.There is a significant difference in the salivary pH variation elicited by the new GSSS in patients with Sjögrens syndrome
2.There is a significant difference in the stimulation of whole saliva secretion capacity elicited by the new GSSS with patients with Sjögrens syndrome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee at the Faculty of Dentistry of the University of Lisbon and the Portuguese Institute for Rheumathological Diseases approved in December 2009

Study design
Two-arm parallel single centre triple-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary Sjögren's syndrome

Interventions

Salivary buffering capacity will be assessed in all participants at baseline. The participants will randomly be allocated to the control and intervention arms in equal numbers (40 in each arm):
1. Intervention arm: New Gustatory stimulant of salivary secretion - one lozenge of Dentaid® (Dentaid, Spain)
2. Control arm: Traditional, citric acid based gustatory stimulant of salivary secretion - one lozenge of SST® (Sinclair, UK)

Salivary secretion rate and pH changes will be recorded at defined time intervals (minute 0, 1, 2, 3, 5, 8, 10, 15 and 20) to determine the efficacy of saliva stimulation and dental erosion potential of these lozenges.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dentaid®, SST®

Primary outcome measure
Time of GSSS induced pH drop below 5.5 expressed in minutes as the mean ± 95% confidence interval. In order to better quantify risk differences of GSSS induced pH drop below 5.5 a contingency table compiling the counts of subjects with pH drops below 5.5 for over one minute will be obtained. Additional analyses will be done to calculate association measures like the absolute risk reduction (ARR) and number needed to treat (NNT).

Secondary outcome measures
1. GSSS induced salivary pH variations expressed as the mean ± 95% confidence interval of the three pH measures obtained from salivary samples at defined time points
2. GSSS stimulated salivary flow expressed in ml/min as the mean ± 95% confidence interval of stimulated salivary flow obtained at different time points
3. Overall stimulated salivary flow will also be calculated and expressed in ml/min as the mean ± 95% confidence interval of the total volume of stimulated saliva divided by the total time of each experiment which will be 20 minutes
4. Salivary stimulation output defined as the difference between GSSS and basal salivary flow, expressed as ml/min

Overall study start date
07/01/2010

Completion date
07/10/2010

Eligibility

Key inclusion criteria

1. Participants (both males and females) above 18 years
2. Suffering from primary Sjögren's syndrome
3. An unstimulated whole saliva flow less than 0.1 mL/min, and a stimulated whole saliva flow greater than 0.2 mL/min

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Currently taking xerostomic medication
2. Pregnant

Date of first enrolment
07/01/2010

Date of final enrolment
07/10/2010

Locations

Countries of recruitment
Portugal

Study participating centre
Grupo de Investigação em Biologia e Bioquímica Oral
Lisbon
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1649-003

Sponsor information

Organisation

Dentaid, S.L. (Spain)

Sponsor details
Oficinas centrales
Ronda Can Fatjó, 10
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Sponsor type
Industry

Website
http://www.dentaid.com/

ROR
https://ror.org/02n9shp96

Funder(s)

Funder type
Industry

Funder Name
Dentaid, S.L. (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration