

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

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| Submission date 03/01/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 16/03/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 16/03/2010 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 Dentaaid 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 Dentaïd® (Dentaïd, 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)

Dentaïd®, SST®

Primary outcome measure

Time of GSSS induced pH drop below 5.5 expressed in minutes as the mean \pm 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 \pm 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 \pm 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 \pm 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

Portugal

1649-003

Sponsor information**Organisation**

Dentaid, S.L. (Spain)

Sponsor details

Oficinas centrales
Ronda Can Fatjó, 10
Parc Tecnologic Del Valles
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dentaid@dentaid.es

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