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

Submission date	Recruitment status	[_] Prospectively registered
27/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2010	Oral Health	

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: 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. However, clinical studies on this issue are lacking. More recently a new class of these products has been marketed with the claim that its lower acid content and addition of fluoride and xylitol diminishes the risk for dental erosion.

The research questions addressed by this study were to find out if this new class of gustatory stimulants of salivary secretion has comparable efficiency in stimulating salivary secretion and do in fact represent a lower risk for dental erosion. The study hypotheses were:
1. There is a significant difference in the salivary pH variation elicited by the two gustatory stimulants of salivary secretion
2. There is a significant difference in the salivary secretion stimulation capacity elicited by the two gustatory stimulants of salivary secretion

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee at the Higher Institute of Health Sciences Egas Moniz (Instituto Superior de Ciências da Saúde Egas Moniz) approved in October 2006

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)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Xerostomia

Interventions

Salivary buffering capacity was assessed in all participants at baseline. The participants were randomly allocate to the control and intervention arms in equal numbers (60 in each arm):
1. Intervention arm: Gustatory stimulant of salivary secretion with xylitol and fluoride - one lozenge of Xerodent® (Alpharma, Sweden)
2. Control arm: Traditional, citric acid based gustatory stimulant of salivary secretion - one lozenge of SST® (Sinclair, UK)

Salivary secretion rate and pH changes were 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)
Xerodent®, SST®

Primary outcome measure
The following were assessed based on the salivary secretion rate and pH changes recorded at minute 0, 1, 2, 3, 5, 8, 10, 15 and 20 during the interventions (see interventions section):
1. GSSS induced salivary pH variations
2. Time of GSSS induced pH drop below 5.5
3. Absolute risk reduction (ARR) and number needed to treat (NNT), based on the pH variations (see primary outcomes 1 and 2 above)
4. GSSS stimulated salivary flow

Secondary outcome measures
Salivary secretion capacity defined as the difference between mechanically stimulated and basal salivary flow, expressed as ml/min.

Overall study start date
02/09/2007

Completion date
02/05/2008

Eligibility

Key inclusion criteria
1. Participants (both males and females) aged over 18 years
2. Students of a Portuguese University through
3. Healthy

Recruitment was supervised by research assistants.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Presence of systemic pathology
2. Currently taking xerostomic medication

Date of first enrolment
02/09/2007

Date of final enrolment
02/05/2008

Locations

Countries of recruitment
Portugal

Study participating centre
Faculdade de Medicina Dentária
Lisboa
Portugal
1649-003 LX

Sponsor information

Organisation
University of Lisbon (Portugal)

Sponsor details
Unidade de Investigação em Ciências Orais e Biomédicas (UICOB)
Faculdade de Medicina Dentária
Universidade de Lisboa
Cidade Universitária

Lisboa
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Sponsor type
University/education

ROR
https://ror.org/01c27hj86

Funder(s)

Funder type
University/education

Funder Name
University of Lisbon (Portugal) - Oral and Biomedical Sciences Research Unit (Unidade de Investigação em Ciências Orais e Biomédicas)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2009		Yes	No