

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

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<b>Registration date</b> 09/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/01/2010	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## 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

### **Study type(s)**

Quality of life

### **Health condition(s) or problem(s) studied**

Xerostomia

### **Interventions**

Salivary buffering capacity was assessed in all participants at baseline. The participants were randomly allocated 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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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)

### 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

### 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?
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[Results article](#)

results

01/04/2009

Yes

No