# Effects of gustatory stimulants of salivary secretion on the pH and stimulation of saliva of patients with head and neck cancer after radiotherapy

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
06/06/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/03/2012	Completed	Results
Last Edited	Condition category	<ul><li>Individual participant data</li></ul>
19/01/2016	Oral Health	Record updated in last year

#### Plain English summary of protocol

Background and study aims

Saliva (spit) washes your teeth and protects them from decay. Radiotherapy treatment for head and neck cancer often reduces the amount of saliva you can make. Gustatory stimulants of salivary secretion (GSSS) are lozenges that are sold over the counter in many European countries and used to stimulate secretion of saliva. However, their acidic nature may increase the risk of dental erosion. The aim of this study is to find out whether the use of the new Dentaid GSSS lozenge increases salivary secretion and is safer regarding dental erosion.

Who can participate?

Patients aged 18 and over with head and neck cancer treated with radiotherapy.

What does the study involve?

Participants are randomly allocated to either the intervention or the control group. Participants in the intervention group are treated with Dentaid lozenges. Participants in the control group are treated with a traditional citric-based galenic formulation. Salivary secretion rate and pH changes are recorded at defined time intervals (minute 0, 1, 2, 3, 5, 8, 10, 15 and 20) to determine the effectiveness of saliva stimulation and the dental erosion potential of these lozenges.

What are the possible benefits and risks of participating? There are no risks to the participants in this study

Where is the study run from?
Portuguese Institute of Oncology (Portugal)

When is the study starting and how long is it expected to run for? July 2011 to July 2012

Who is funding the study? Dentaid (Spain)

Who is the main contact? Prof. António Mata duartemd@yahoo.co.uk

# Contact information

### Type(s)

Scientific

#### Contact name

Prof António Mata

#### Contact details

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# Additional identifiers

Protocol serial number

N/A

# Study information

#### Scientific Title

Effects of gustatory stimulants of salivary secretion on the pH and stimulation of saliva of patients with head and neck cancer after radiotherapy: a two-arm cross-over 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 slivary 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 Sndrome
- 2. There is a significant difference in the stimulation of whole saliva secretion capacity elicited by

the new GSSS with patients with Sjögrens syndrome

3. There is a significant difference in unstimulated and stimulated whole saliva secretion after radiation in patients with head and neck cancer

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Dentistry College of the University of Lisbon, May 2011, ref: 2/2011

#### Study design

Two-arm cross-over single-centre blind randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

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

Dental erosion in patients with head and neck cancer after radiotherapy

#### 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):

Intervention arm: new gustatory stimulant of salivary secretion - one lozenge of Dentaid® (Dentaid, Spain)

Control arm: traditional citric based galenic formulation

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

Other

#### Phase

Not Applicable

#### Primary outcome(s)

- 1. Time of GSSS induced pH drop below 5.5 expressed in minutes as the mean  $\pm$  95% confidence interval
- 2. 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
- 3. Additional analyses will be done to calculate association measures like the absolute risk reduction (ARR) and number needed to treat (NNT)

#### Key secondary outcome(s))

- 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

#### Completion date

30/07/2012

# **Eligibility**

#### Key inclusion criteria

- 1. Participants (both males and females) above 18 years
- 2. Patients after head and neck radiotherapy
- 3. An unstimulated whole saliva flow less than 0.1 mL/min
- 4. A stimulated whole saliva flow greater than 0.2 mL/min

## Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Pregnant
- 2. Does not meet inclusion criteria

#### Date of first enrolment

01/07/2011

#### Date of final enrolment

30/07/2012

# Locations

#### Countries of recruitment

Portugal

# Study participating centre Universidade de Lisboa Lisbon Portugal

Portugal 1649-003

# Sponsor information

## Organisation

Dentaid (Spain)

#### **ROR**

https://ror.org/02n9shp96

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Dentaid (Spain)

# **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?

Participant information sheet Participant in

Participant information sheet 11/11/2025 11/11/2025 No

Yes