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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
06/06/2011

Recruitment status
No longer recruiting

Registration date
29/03/2012

Overall study status
Completed

Last Edited
19/01/2016

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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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 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
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 measure
1. Time of GSSS induced pH drop below 5.5 expressed in minutes as the mean ± 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)

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
01/07/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

80

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
1649-003

Sponsor information

Organisation
Dentaid (Spain)

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

Website
http://www.dentaid.es/

ROR
https://ror.org/02n9shp96

Funder(s)

Funder type
Industry

Funder Name
Dentaid (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