ISRCTN14942820 https://doi.org/10.1186/ISRCTN14942820

# The effect of a calcium delivery system on tooth decay in head and neck cancer patients treated by radiotherapy

**Submission date**
25/10/2017

**Recruitment status**
No longer recruiting

**Registration date**
31/10/2017

**Overall study status**
Completed

**Last Edited**
01/11/2017

**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
Nasopharyngeal carcinoma (NPC) is a type of head and neck cancer that starts in the upper part of the throat behind the nose. It is the most common head and neck cancer affecting Singapore men and is primarily treated with radiotherapy. The major side-effects of radiotherapy are dry mouth, increased saliva acidity and increased bacterial count, which significantly increase the risk of dental caries (tooth decay). Casein phosphopeptide amorphous calcium phosphate (CPP-ACP) is a milk product which helps in remineralization and prevents dental caries. Its effectiveness has been shown in the healthy population but its benefit for NPC patients has not yet been established. At the National Dental Centre Singapore (NDCS), the standard treatment for the control of dental caries in NPC patients treated with radiotherapy is the life-long daily use of 0.4% stannous fluoride gel. However, clinicians have noticed that these patients are still experiencing tooth decay. Therefore, the aim of this study is to assess the effect of CPP-ACP on dental caries progression at the tooth surface level in NPC patients treated with radiotherapy when used together with the standard fluoride gel.

Who can participate?
Patients aged 21 years or older who have been diagnosed with NPC and are undergoing radiotherapy for the first time

What does the study involve?
Participants are randomly allocated to one of two groups. The control group receive standard fluoride gel and a placebo (dummy) creme whilst the intervention group received the standard fluoride gel and CPP-ACP creme. All participants are reviewed at five study visits: two visits before the start of radiotherapy, mid-radiotherapy, 2 weeks and 3 months after the end of radiotherapy. At each study visit, an oral examination is carried out. Saliva is collected and tested for fluoride levels.

What are the possible benefits and risks of participating?
The study aims to increase knowledge of the effect of CPP-ACP on caries lesion progression at the tooth surface level, which may improve the future treatment and management of caries in

NPC patients. If CPP-ACP does become effective for those participants who receive it, the participant may have a reduced risk of dental caries while he/she is in the study. All participants are provided with a SGD$40 transport allowance when he/she returns for each study visit. In addition, all oral care products such as the standard fluoride gel, creme, fluoride toothpaste and toothbrush are provided free of charge. The review charges of the study visits are also waived. CPP-ACP is made from casein, a milk protein, so potential participants with a known allergy to milk casein or hydroxybenzoate preservatives are not allowed to participate in the study. If a participant experiences any allergic reaction to the fluoride gel and/or creme, the participant should immediately seek medical advice, stop using the oral care products and inform the attending dentist and study co-ordinator.

Where is the study run from?
National Dental Centre Singapore

When is the study starting and how long is it expected to run for?
January 2010 to August 2011

Who is funding the study?
National Dental Centre Singapore Research Fund/National Medical Research Council Centre Grant

Who is the main contact?
Dr Christina Sim
christina.sim.poh.choo@singhealth.com.sg

# Contact information

### Type(s)
Public

### Contact name
Dr Edwin Liu

### Contact details
National Dental Centre Singapore
5, Second Hospital Avenue
Singapore
Singapore
168938

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
CIRB 2010/182/D

# Study information

## Scientific Title
Anticariogenic efficacy of a saliva biomimetic in a randomised trial of head-and-neck cancer patients undergoing radiotherapy

## Study objectives
The null hypothesis is that there is no difference in caries progression at tooth surface level between the intervention group and the placebo group

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Singapore Health Centralised Institutional Review Board, 30/04/2010, ref: 2010/182/D

## Study design
Randomized double-blind study

## 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 to request a patient information sheet

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

## Interventions
Randomisation was carried out based on a randomisation list generated by the biostatistician. 24 nasopharyngeal carcinoma patients treated with radiotherapy were randomly assigned to the control group (fluoride gel + placebo creme) or the intervention group (fluoride gel + casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) creme). All participants are reviewed at five study visits: two visits before start of radiotherapy, mid-radiotherapy, 2 weeks and 3 months after end of radiotherapy. At each study visit, an oral examination was carried out. Resting saliva was collected and analysed for fluoride ion concentration.

## Intervention Type
Other

### Primary outcome measure
Caries lesion progression assessed using the International Caries Detection and Assessment System (ICDAS) visual criteria at baseline, 2 weeks and 3 months after completion of radiotherapy

### Secondary outcome measures
Fluoride ion concentration in resting saliva measured using a fluoride-specific electrode at baseline, one week before start of radiotherapy, mid-radiotherapy, 2 weeks and 3 months after end of radiotherapy

### Overall study start date
10/01/2010

### Completion date
15/08/2011

## Eligibility

### Key inclusion criteria
1. Patients aged 21 years or older
2. Ability to understand and provide informed consent prior to starting the study
3. Patient has no advanced periodontal disease
4. Patient has at least eight remaining teeth at start of the study

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
24

### Key exclusion criteria
1. Patient who has previously undergone head and neck radiotherapy
2. Uncontrolled systemic disease (eg hypertension, diabetes)
3. Patient on palliative care
4. Pregnancy (self declared)
5. Patient with milk allergy (self declared)
6. Patient with hydroxybenzoates (preservative) allergy (self declared)

### Date of first enrolment
31/05/2010

### Date of final enrolment
01/02/2011

# Locations

**Countries of recruitment**
Singapore

**Study participating centre**
**National Dental Centre Singapore**
Singapore
168938

# Sponsor information

**Organisation**
National Dental Centre Singapore

**Sponsor details**
5, Second Hospital Avenue
Singapore
Singapore
168938

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/03w6pea42

# Funder(s)

**Funder type**
Research council

**Funder Name**
National Dental Centre Singapore Research Fund/National Medical Research Council Centre Grant

# Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal. The details of the protocol will be submitted together with the manuscript submission to the journal.

## Intention to publish date
31/12/2017

## Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary
Data sharing statement to be made available at a later date