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Clinical trial of fluoride varnish in preventing dental caries of Sjögren's syndrome patients

Submission date
08/09/2016

Recruitment status
No longer recruiting

Registration date
09/09/2016

Overall study status
Completed

Last Edited
26/09/2016

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Sjögren's syndrome is an autoimmune disorder where the body's immune system attacks glands that secrete fluid, such as the salivary glands. This leads to a reduced production of saliva, making patients more prone to tooth decay (caries). Fluoride varnish is commonly applied onto their teeth for caries prevention. The aim of this study is to investigate the effectiveness of fluoride varnish in caries prevention in this group of patients.

Who can participate?
Sjögren's syndrome patients aged 18 or over with eight or more natural teeth.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group have their teeth treated with fluoride varnish quarterly and participants in the other group have their teeth treated with a placebo (dummy) gel quarterly. Their teeth are assessed for caries at the start of the study and after 12 and 24 months, along with the amount of Candida (a fungus) and lactobacilli (bacteria) in the mouth.

What are the possible benefits and risks of participating
Participants are provided with free-of-charge dental examinations, oral hygiene instructions, dental treatment (restorations and prostheses), and periodontal (gum) treatment if needed. There is a temporary effect of fluoride varnish as it leaves a yellow film on the teeth for several hours after application unless it is removed by brushing.

Where is the study run from?
Prince Philip Dental Hospital, Faculty of Dentistry, The University of Hong Kong (Hong Kong)

When is the study starting and how long is it expected to run for?
January 2009 to October 2013

Who is funding the study
Research Grants Council of Hong Kong (Hong Kong)

Who is the main contact?
Dr Katherine Leung

Contact information

Type(s)
Scientific

Contact name
Dr Katherine Leung

ORCID ID
http://orcid.org/0000-0003-3703-8232

Contact details
Prosthodontics
Prince Philip Dental Hospital
34 Hospital Road
Sai Ying Pun
Hong Kong
Hong Kong
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized, double-blind, placebo-controlled clinical trial of fluoride varnish in preventing dental caries of Sjögren’s syndrome patients

Study objectives
Quarterly applied fluoride varnish can prevent caries development in Sjögren’s syndrome patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Institutional Review Boards of the University of Hong Kong/Hospital Authority Hong Kong West and Kowloon Central and East Clusters, 23/04/2008, refs: UW 08-167 and KC/KE-10-0014/ER-2

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Caries development in Sjögren's syndrome patients

Interventions
Sjögren's syndrome patients were randomly assigned to receive either professionally applied fluoride varnish or placebo gel quarterly. Development and arrest of caries at the coronal and root surfaces were recorded at 12 months and 24 months and compared to that of the baseline. Effect of fluoride varnish on oral Candida and lactobacilli colonization was explored by comparing baseline oral microbiological assessments to data obtained at 12 months and 24 months.

Intervention Type
Other

Primary outcome measure
Caries at the coronal and root surface evaluated using the International Caries Detection and Assessment System (ICDAS) at 12 months and 24 months

Secondary outcome measures
Counts of lactobacilli and Candida (expressed as colony forming units per milliliter (CFU/ml) in salivary samples and colony forming units per gram in dental plaque samples) evaluated at 12 months and 24 months

Overall study start date
03/01/2009

Completion date
30/10/2013

Eligibility

Key inclusion criteria
1. Clinical diagnosis of Sjögren's syndrome established using the American-European Consensus Group (AECG) criteria at least 6 months before the commencement of this study
2. Age 18 or above
3. Had 8 or more natural teeth present

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Severe periodontal disease (e.g., periodontal pockets were deeper than 6 mm) at two or more sextants
2. Received therapeutic irradiation to the head and neck region
3. Had concurrent systemic illness (except connective tissue disorder associated with secondary Sjögren's syndrome)
4. Taking medication that altered salivary flow
5. Had participated in a clinical trial within 6 months before commencement of this trial

Date of first enrolment
11/06/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Hong Kong

Study participating centre
Prince Philip Dental Hospital
Faculty of Dentistry
The University of Hong Kong

34 Hospital Road
Sai Ying Pun
Hong Kong
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Sponsor information

Organisation
Research Grants Council of Hong Kong

Sponsor details
7/F., Shui On Centre
6-8 Harbour Road
Wanchai
Hong Kong
Hong Kong
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Sponsor type
Research council

ROR
https://ror.org/00djwmt25

Funder(s)

Funder type
Research council

Funder Name
Research Grants Council, University Grants Committee

Alternative Name(s)
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Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Publication and dissemination plan
A manuscript has been submitted to be considered for publication

Intention to publish date
08/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/09/2016		Yes	No