

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

<b>Submission date</b> 08/09/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/09/2016	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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**  
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**Contact details**  
Prosthodontics  
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## Additional identifiers

**Protocol serial number**  
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

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

Prevention

### **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(s)**

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

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

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**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

**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

### 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?
<a href="#">Results article</a>	results	23/09/2016		Yes	No