

# Is toothpaste containing xylitol + fluoride more effective than toothpaste containing only fluoride in preventing dental caries among pre-schoolers?

<b>Submission date</b> 18/11/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/11/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims:

Dental caries (tooth decay) is the most common disease among pre-schoolers. Low-income pre-schoolers are more likely to be at risk for tooth decay. Current public health strategies have failed to significantly control tooth decay in this age group. This is an important problem to address because untreated tooth decay leads to pain, infection, which can lead to poor academic outcomes, systemic health problems, cellulitis, and in rare cases, death.

Currently, fluoride toothpaste is used to prevent tooth decay in pre-schoolers. Studies suggest that xylitol, a naturally-occurring sweetener, also helps to prevent tooth decay. Based on the idea that adding xylitol to fluoride toothpaste leads to a more effective product, toothpaste manufacturers have developed a xylitol+fluoride toothpaste. However, until now, no studies have been conducted that compare fluoride toothpaste to xylitol+fluoride toothpaste as a way to prevent tooth decay in pre-schoolers. The Head Start Program is a national program targeted at low-income pre-schoolers ages 3-5 years. The aim of the program is to prepare vulnerable pre-schoolers for kindergarten by ensuring good overall health. Many Head Start Programme classrooms include a tooth brushing program that is overseen by the classroom teacher. Teachers are trained to ensure the pre-schoolers follow the correct tooth brushing method. Currently, all Head Start classrooms that have a tooth brushing program use fluoride toothpaste.

### Who can participate?

Pre-schoolers are healthy and that consent is received for participation by the pre-schoolers caregiver.

### What does the study involve?

This study will introduce xylitol-fluoride toothpaste to two Head Start classrooms and fluoride-toothpaste to two other Head Start classrooms. Our aim is to compare tooth decay rates for pre-schoolers in the two groups, from the start of the study to 9 months. We will also collect plaque and saliva samples at 9 months to see if the two groups differ in the levels of *Streptococcus mutans*, the bacteria which is responsible for plaque and tooth decay.

What are the possible benefits and risks of participating?

Pre-schoolers participating may be less likely to experience tooth decay. All tooth brushing activities were directly supervised by multiple classroom teachers, so the risks to the pre-schoolers were minimal.

Where is the study run from?

From four Head Start Programme classrooms in Majuro in the Republic of the Marshall Islands (50 pre-schoolers per classroom).

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

The study took place during the 2010/2011 school year.

Who is funding the study?

United States Health Resources and Services Administration - Targeted Oral Health Services Systems.

Who is the main contact?

Dr Ohnmar Tut

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Ohnmar Tut

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

Scientific Title

A clinical trial comparing fluoride toothpaste and xylitol+fluoride toothpaste in reducing dental caries among pre-schoolers at increased risk for tooth decay: a randomised prospective trial

**Study objectives**

Xylitol+fluoride toothpaste is more effective than fluoride toothpaste at slowing the rates of tooth decay progression in pre-schoolers

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Single-center double-blinded classroom randomized prospective clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**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 caries

**Interventions**

Arm 1: supervised in-class toothbrushing once/day with xylitol+1400ppm fluoride toothpaste

Arm 2: supervised in-class toothbrushing once/day with 1400ppm fluoride toothpaste

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Total increase in the number of primary tooth surfaces with untreated dental caries from baseline to end of school year

**Secondary outcome measures**

Levels of intraoral plaque and salivary mutans streptococci (at end of school year)

**Overall study start date**

01/09/2010

**Completion date**

30/06/2011

## **Eligibility**

**Key inclusion criteria**

1. Enrolled in one of four pre-schools in Majuro, Marshall Islands
2. Under age 5
3. Parent consent to participate in the trial

**Participant type(s)**

Patient

**Age group**

Child

**Upper age limit**

5 Years

**Sex**

Both

**Target number of participants**

200 participants

**Total final enrolment**

196

**Key exclusion criteria**

Allergy or sensitivity to fluoride toothpaste

**Date of first enrolment**

01/09/2010

**Date of final enrolment**

30/06/2011

## **Locations**

**Countries of recruitment**

Marshall Islands

**Study participating centre**

## **Republic of the Marshall Islands**

Majuro

Marshall Islands

96960

## **Sponsor information**

### **Organisation**

Republic of the Marshall Islands (Marshall Islands)

### **Sponsor details**

c/o Dr Ohnmar Tut

Ministry of Health

Post Office Box 16

Majuro

Marshall Islands

96960

### **Sponsor type**

Government

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

United States Health Resources and Services Administration (HRSA) (USA) - Targeted Oral Health Services Systems TOHSS Grant ref: H47MC08647

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

Not provided at time of registration

### **IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/01/2014	03/11/2022	Yes	No