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

Submission date
18/11/2011

Recruitment status
No longer recruiting

Registration date
06/01/2012

Overall study status
Completed

Last Edited
03/11/2022

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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
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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?
Results article		01/01/2014	03/11/2022	Yes	No