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Xylitol in milk to prevent tooth decay in children

Submission date 28/02/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/03/2014	**Overall study status** Completed	
Last Edited 10/07/2015	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Since 1983, Peru's Glass of Milk Program has targeted schools in low-income communities and provides every low-income child with a daily glass of milk. While the program has good public health intentions, milk for young children in Peru is sweetened with table sugar (sucrose) and honey, which exposes children already at high risk for dental disease to additional sugar. Xylitol is a safe and acceptable sugar substitute that reduces Streptococcus mutans, the main bacteria linked to dental caries. However, studies to date have not tested whether xylitol in milk is an effective community-based strategy to prevent caries (tooth decay) in vulnerable children. This study will compare xylitol milk with sorbitol milk and sucrose milk.

Who can participate?
Children in kindergarten through third grade studying in the participating school can take part in the study.

What does the study involve?
The children will be randomly allocated to receive either xylitol in their milk once or twice per day, sorbitol in their milk once or twice per day, or sucrose in their milk once per day. The increase in dental caries (in both the primary molars and permanent first molars) and the level of the bacteria S. mutans will be measured after 10 months.

What are the possible benefits and risks of participating?
A potential benefit is the fact that all children will receive a dental screening. Any children with dental disease will be sent home with a letter that summarizes the child's oral health status, any recommendations for treatment, and a referral to a local dental clinic (if needed). Another potential benefit is reduced tooth decay rates for children in the experimental groups (xylitol or sorbitol). In terms of risks, there is a very small chance that a child could develop minor stomach discomfort from taking in large doses of xylitol. The child might also find the dental examination to be uncomfortable.

Where is the study run from?
This study will be conducted at I.E. San Jose de Cottolengo School, Arequipa, Peru.

When is study starting and how long is it expected to run for?
The study will start in March 2014 and will run until December 2014. We will recruit participants for one week (10th March-14th March).

Who is funding the study?
International Association of Dental Research (USA).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Peru's Glass of Milk Program (Programa Social Vaso de Leche): Using xylitol in milk in a community-based nutrition program to prevent dental caries in children

Study objectives
Our main study hypothesis is that adding xylitol to milk will be more efficacious at preventing tooth decay in children than sorbitol or sucrose. Our secondary hypothesis is that adding xylitol to milk will be more efficacious at reducing intraoral levels of tooth decay-causing bacteria than sorbitol or sucrose.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the Universidad Católica de Santa Maria, 02/02/2014
University of Washington IRB, 12/03/2014

Study design
Prospective randomised five-arm trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

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
Tooth decay (dental caries)

Interventions
1. Xylitol in milk (twice per day)
2. Xylitol in milk (once per day)
3. Sorbitol in milk (twice a day)
4. Sorbitol in milk (once per day)
5. Sucrose in milk (once per day)

The total duration of the intervention is about 9 months (March 2014 to December 2014). There is one baseline exam (March) and one end-of-study exam (December).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Caries increment (in primary molars and permanent first molars) from baseline to end of study

Both outcomes will be measured twice: at baseline (in March 2014 before children are randomized into one of the five milk arms) and at end-of study (in December 2014 when the intervention will end). Dental caries will be measured using World Health Organization caries

criteria, which is approved for use by the U.S. National Institute of Dental and Craniofacial Research (NIDCR), the main federal funding agency in the U.S. for dental research. Intraoral bacterial levels will be enumerated twice (at baseline in March 2014 and when the intervention ends in December 2014) using standard microbiological mutan streptococci enumeration techniques.

Secondary outcome measures
Streptococcus mutans levels change from baseline to end of study

Overall study start date
07/03/2014

Completion date
20/12/2014

Eligibility

Key inclusion criteria
1. Grades K to 3 (ages 4 to 10 years) at baseline
2. Attend the I.E. San Jose de Cottolengo School in the district of Melgar, Arequipa, Peru

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. If the child has been taking antibiotics during the last four weeks from baseline
2. No caregiver consent or child assent
3. Allergy to milk or lactose intolerant
4. Unable to cooperate for a dental exam

Date of first enrolment
10/03/2014

Date of final enrolment
14/03/2014

Locations

Countries of recruitment
Peru

United States of America

Study participating centre
1959 NE Pacific Street, B509f
Seattle
United States of America
98195

Sponsor information

Organisation
International Association of Dental Research (USA)

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Sponsor type
Research organisation

ROR
https://ror.org/008vgd385

Funder(s)

Funder type
Research organisation

Funder Name
International Association of Dental Research (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration