

# Xylitol in milk to prevent tooth decay in children

<b>Submission date</b> 28/02/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/07/2015	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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?  
Dr Donald Chi  
dchi@uw.edu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Donald Chi

**Contact details**  
1959 NE Pacific Street, B509f  
Seattle  
United States of America  
98195  
+1 (0)206 616 4332  
dchi@uw.edu

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Prevention

**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(s)**

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.

**Key secondary outcome(s)**

Streptococcus mutans levels change from baseline to end of study

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

4 years

**Upper age limit**

10 years

**Sex**

All

**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)

**ROR**

<https://ror.org/008vgd385>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

International Association of Dental Research (USA)

**Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration