

# Xylitol for healthy teeth and ears project

<b>Submission date</b> 07/02/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/08/2011	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Peter Milgrom

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R40 MC03622

## Study information

Scientific Title

Xylitol for acute otitis media and early childhood caries

### **Study objectives**

Xylitol syrup reduces the incidence of dental caries and acute otitis media

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

University of Washington Institutional Review Board, initial approval granted on 19 July 2005 (ref: HSD# 04-4039-B 01). The approval has been renewed annually on 17 August 2006 (ref: HSD# 04-4039-B 02) and 12 August 2007 (ref: HSD# 04-4039-B 03).

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

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

Prevention

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Dental caries and acute otitis media

### **Interventions**

Three group design:

1. Xylitol syrup 8 g/day divided into 2 doses + 1 dose of sorbitol = 3 doses/day
2. Xylitol syrup 8 g/day divided into 3 doses + 0 dose of sorbitol = 3 doses/day
3. Xylitol syrup 2.66 g/day in a single dose (positive control) + 2 doses of sorbitol = 3 doses/day

Duration of interventions: 12 months

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Xylitol

**Primary outcome measure**

1. Dental caries, assessed at baseline (at randomization), mid study (5-6 months), and 12 months (end of study period)
2. Acute otitis media (incidence rate). Children were assessed as symptoms suggestive of acute otitis media arose throughout the follow-up period (12 months)

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/04/2006

**Completion date**

15/01/2008

## Eligibility

**Key inclusion criteria**

Children aged 6-15 months of age living in Laura or Delap district of Majuro Atoll, the Marshall Islands

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

15 Months

**Sex**

Both

**Target number of participants**

102

**Key exclusion criteria**

Children with known gastrointestinal problems

**Date of first enrolment**

01/04/2006

**Date of final enrolment**

15/01/2008

## Locations

**Countries of recruitment**

Marshall Islands

United States of America

**Study participating centre**

**Dental Public Health Sciences**

Seattle

United States of America

98195

## **Sponsor information**

**Organisation**

University of Washington (USA)

**Sponsor details**

c/o Ms Carol Zuiches

University of Washington

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**Sponsor type**

University/education

**Website**

<http://www.washington.edu/research/osp/index.php>

**ROR**

<https://ror.org/00cvxb145>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Maternal and Child Health Bureau - Health Resources and Services Administration (MCHB - HRSA) (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2009		Yes	No