ISRCTN84269958 https://doi.org/10.1186/ISRCTN84269958

# Xylitol for healthy teeth and ears project

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|---|---|---|
| **Submission date**<br>07/02/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>26/02/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>31/08/2011 | **Condition category**<br>Oral Health | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

### Study type(s)
Prevention

### 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(s)
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)

### Key secondary outcome(s))
No secondary outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
6 months

### Upper age limit
15 months

### Sex
All

### 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)

**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

## 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? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2009 | | Yes | No |