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Xylitol for healthy teeth and ears project

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

Primary study design
Interventional

Study design
Randomised controlled trial

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