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Xylitol clinical studies for prevention: In-school xylitol gummy bear snack study

Submission date	Recruitment status	[_] Prospectively registered
07/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/07/2008	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
U54 DE14254

Study information

Scientific Title
School-based xylitol gummy bears snacks: a randomized controlled trial

Study objectives
Consumption of xylitol gummy snacks reduces S. mutans and Lactobacillus spp. levels

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Washington Internal Review Board. Date of approval: 27 March 2007 (ref: HS # 07-4857-B 01)

Primary study design
Interventional

Study design
Randmised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dental caries

Interventions
Randomisation was carried out at the level of individuals. Gummy bear snacks were packaged by the unit-dose and labeled specific to the students ID number which corresponded with the individual randomization.

Three-group design:
Group 1: Xylitol gummy bears, 11.7 g/day xylitol
Group 2: Xylitol gummy bears, 15.6 g/day xylitol
Group 3: Maltitol gummy bear (control)

All groups consumed gummy bears 3 times/day for 6 weeks in the classroom during school hours only.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
xylitol

Primary outcome(s)
S. mutans and Lactobacillus spp. levels in plaque samples at enrollment (baseline) and 6 weeks (end of study).

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/06/2007

Eligibility

Key inclusion criteria
Children attending First through Fifth grade at two elementary schools in rural Washington State, USA

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Children with gastrointestinal problems

Date of first enrolment
01/04/2007

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
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
Research organisation

Funder Name
National Institute of Dental and Cranio-facial Research (NIDCR, USA; ref: U54 DE14254)

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	25/07/2008		Yes	No