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Xylitol Clinical Studies for Prevention - Xylitol Snack Foods among Adults Study (Gum 3)

Submission date 16/11/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 02/12/2005	**Overall study status** Stopped	
Last Edited 20/08/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U54 DE14254

Study information

Scientific Title

Acronym
Gum 3

Study objectives
Reduction in mutans strepotococci by xylitol snack foods is equivalent to xylitol chewing gum among adults

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Washington Internal Review Board - Application#: 05-5945-B 01. Approved 29/03 /2005.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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

Interventions
Please note that this trial was stopped during the recruitment phase due to reconsideration of power calculations and insufficient resources. An alternative approach to gaining the information was used and the results have been published in http://www.ncbi.nlm.nih.gov /pubmed/18267030.

Interventions:
Two group design with positive control. Equivalence study, xylitol Gummy Bears (10.4 g/day) compared to xylitol chewing gum (10.3 g/day).

Intervention Type

Drug

Phase
Not Specified

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

Primary outcome measure
Reduction in mutans streptococci level in plaque

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/05/2005

Completion date
01/04/2006

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Adult, male & female, with screening plaque mutans streptococci level greater than 10,000 CFU /ml

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Gastro-intestinal diseases/problems
2. Phenylalanine intolerant

Date of first enrolment
15/05/2005

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
United States of America

Study participating centre
Dental Public Health Sciences
Seattle, Washington
United States of America
98195

Sponsor information

Organisation
University of Washington (USA)

Sponsor details
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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
National Institute of Dental and Cranio-facial Research (NIDCR) (USA), ref: U54 DE14254

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