

Xylitol Clinical Studies for Prevention - Xylitol Frequency Study (Gum 2)

Submission date 16/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/10/2009	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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 2

Study objectives

Increasing reduction in mutans streptococci level in plaque and saliva to increasing frequency of xylitol use at the same total daily dose.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Washington Internal Review Board - Application#: 04-2024-B 01. Approved 17/06 /2004.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Dental caries

Interventions

4 group design. Control (sorbitol gum) group and 3 xylitol gum groups who consumed 10.32 g xylitol per day. All 4 groups chewed 12 pellets of gum per day. Xylitol groups evenly divided the 12 gums into 2, 3, or 4 chewing frequency. Controls chewed sorbitol gums 4 times per day.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Xylitol

Primary outcome measure

Reduction in mutans streptococci level in plaque and saliva

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2004

Completion date

01/03/2005

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

132

Key exclusion criteria

1. Gastro-intestinal diseases/problems
2. Phenylalanine intolerant

Date of first enrolment

01/04/2004

Date of final enrolment

01/03/2005

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
Carol Zuiches
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/03/2006		Yes	No