

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter Milgrom

Contact details
Dental Public Health Sciences
1959 NE Pacific Street
Rm B-509
Box 357475
Seattle, Washington
United States of America
98195
+1 206 685 4183
dfrc@u.washington.edu

Additional identifiers

Protocol serial number
U54 DE14254

Study information

Scientific Title

Acronym

Gum 3

Study objectives

Reduction in mutans streptococci 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

Study type(s)

Prevention

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(s)

Reduction in mutans streptococci level in plaque

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration