ISRCTN43479664 https://doi.org/10.1186/ISRCTN43479664

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

Submission date	Recruitment status	[_] Prospectively registered
16/11/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/10/2009	Oral Health	

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
+1 206 543 4043
dfrc@u.washington.edu

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
Asst Vice Provost for Research
Office of Sponsored Programs
1100 45th St.
NE, Ste. 300
Seattle, Washington
United States of America
98105
+1 206 543 4043
gcsvcs@u.washington.edu

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