ISRCTN73818624 https://doi.org/10.1186/ISRCTN73818624

# Xylitol Clinical Studies for Prevention - Xylitol Dose Study (Gum 1)

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 16/11/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 02/12/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/09/2009 | 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 1

### Study objectives
Increasing reduction in mutans streptococci level in plaque and saliva to increasing dose of xylitol use

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
University of Washington Internal Review Board - Application #: 02-4021-B 02. Approved 02/01 /2003.

### 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
4 group design. Control (sorbitol gum) and 3 xylitol gum groups all chewed 12 pellets of gum evenly divided into 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
01/03/2003

### Completion date
01/06/2004

## 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
01/03/2003

### Date of final enrolment
01/06/2004

## 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) - 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 | 01/02/2006 | | Yes | No |