

# A study of the demineralising potential of cooked Chinese starches with an in situ caries model

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2014	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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Leeds  
United Kingdom  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0436118019

# Study information

## Scientific Title

### Study objectives

To measure the effect on enamel microhardness of three test foods as compared to a 10% sucrose solution and a 10% sorbitol solution.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

## Participant information sheet

### Health condition(s) or problem(s) studied

Oral Health: Cariology

### Interventions

Randomised controlled trial. Random allocation to:

1. Test food one
2. Test food two
3. Test food three
4. 10% sucrose solution
5. 10% sorbitol solution

### Intervention Type

Drug

### Phase

Not Specified

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

10% sucrose solution, 10% sorbitol solution

**Primary outcome measure**

Demineralisation of enamel slabs (assessed by changes in microhardness)

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

24/03/2003

**Completion date**

30/06/2003

## Eligibility

**Key inclusion criteria**

Eight fit and healthy adults recruited from staff of the Leeds Dental Institute, Leeds NHS Trust, Leeds University, students (other than undergraduate dental students) of Leeds University.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

8

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

24/03/2003

**Date of final enrolment**

30/06/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Department of Child Dental Health**  
Leeds  
United Kingdom  
LS2 9LU

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Leeds Teaching Hospitals NHS Trust (UK)

## **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