

# An investigation of odontogenic bacteraemia associated with orthodontic treatment procedures

<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 checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2009	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## 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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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0263092953

# Study information

## Scientific Title

### Study objectives

There may be an increase in the prevalence and intensity of bacteraemia following either debanding or gold chain adjustment, compared with baseline.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised single blind study

### 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

Oral Health: Orthodontics

### Interventions

1. Debanding
2. Adjustment of a gold chain and bracket

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

1. Prevalence of bacteraemia (number of positive blood cultures)
2. Intensity of bacteraemia (number of colony forming units of bacteria per ml blood)
3. Identity of bacteria isolated from blood cultures

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/12/2002

**Completion date**

01/09/2003

## Eligibility

**Key inclusion criteria**

82 patients from Paediatric Dentistry.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

82

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/12/2002

**Date of final enrolment**

01/09/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Oral Surgery Department

London

United Kingdom

WC1X 8LD

# 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

University College London 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2007		Yes	No

