

An investigation of odontogenic bacteraemia associated with orthodontic treatment procedures

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2009	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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?
Results article	results	01/04/2007		Yes	No

