

An investigation of odontogenic bacteraemia associated with orthodontic treatment procedures

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/01/2009	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr VS Lucas

Contact details
Oral Surgery Department
Eastman Dental Hospital
256 Gray's Inn Road
London
United Kingdom
WC1X 8LD
+44 (0)20 7915 1000

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised single blind study

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/09/2003

Eligibility**Key inclusion criteria**

82 patients from Paediatric Dentistry.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Oral Surgery Department

London

United Kingdom

WC1X 8LD

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

University College London Hospitals NHS Trust (UK)

Results and Publications

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