Application of molecular diagnostic methodologies to analyse plaque microbial population shifts associated with placement of fixed orthodontic appliances

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2005	Completed	[X] Results		
Last Edited 16/03/2018	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

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Contact details

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Additional identifiers

Protocol serial number

N0264149440

Study information

Scientific Title

Application of molecular diagnostic methodologies to analyse plaque microbial population shifts associated with placement of fixed orthodontic appliances

Study objectives

Are there shifts from non-pathological to pathological bacterial flora following the placement of fixed orthodontic appliances (braces)

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oral Health: Orthodontics

Interventions

Placement of fixed appliances (braces) - randomised cross mouth allocation of bands

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Changes in the oral microflora, both sub and supra gingival, as a result of orthodontic fixed appliance treatment (braces)

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/01/2006

Eligibility

Key inclusion criteria

25 patients aged 11-14 years about to start treatment with fixed orthodontic appliances

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

11 years

Upper age limit

14 years

Sex

All

Key exclusion criteria

- 1. Patients requiring dental arch expansion
- 2. Heavily restored dentition
- 3. Use of antibiotics in the last 3 months

Date of first enrolment

01/01/2005

Date of final enrolment

01/01/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Bristol Royal Infirmary

Bristol United Kingdom BS2 8HW

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

United Bristol Healthcare NHS Trust

Funder Name

NHS R&D Support Funding

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 adde	d Peer reviewed?	Patient-facing?
Results article	results	01/05/2014	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	5 No	Yes