

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/03/2018	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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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 added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2014		Yes	No