

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2005

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

Age group

Child

Lower age limit

11 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

25

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

England

United Kingdom

Study participating centre

Bristol Royal Infirmary

Bristol

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Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

United Bristol Healthcare NHS Trust

Funder Name

NHS R&D Support Funding

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	01/05/2014		Yes	No