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Investigation of enzymes in gingival crevicular fluid (GCF) and their gene activation profiles during orthodontic treatment

Submission date 29/07/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/08/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/09/2008	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rohaya Megat Abdul Wahab

Contact details
Orthodontic Department
Faculty of Dentistry
Universiti Kebangsaan Malaysia
Jalan Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pulp molecular and gingival crevicular fluid (GCF) enzymological profiles during orthodontic treatment

Study objectives
Enzyme activity will be increased and specific genes will be activated during orthodontic tooth movement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, Faculty of Dentistry, National University of Malaysia (Universiti Kebangsaan Malaysia). Date of approval: 15/06/2007

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Enzyme activity and gene profile during tooth movement

Interventions
1. Assessment of the orthodontic appliance and evaluation of tooth movement at monthly interval (week 4, 8 and 12). The whole orthodontic treatment will be monitored clinically over 2 years.
2. Characterisation of GCF before and after the placement of orthodontic appliances. GCF samples taken at week 1, 2, 3, 4, 6, 8, 11 and 12 at the mesial and distal aspect of test (distalised canine) and control teeth (canine teeth that have not been affected by the orthodontic treatment) after premolar teeth have been extracted
3. Pulp tissues characterisation of extracted teeth at 6 weeks. The test tooth will be the upper first premolar that will be extracted after orthodontic treatment. The control tooth will be a lower first premolar that has not been affected by the orthodontic treatment.
4. Characterisation of mRNA from pulp tissues (as in method 3 above) and determination of mRNA quality for microarray hybridisation

5. Microarray analysis of pulp tissues (as in method 3 above)
6. Bioinformatic analysis of potential genes involved during tooth movement

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Activity of the enzymes and genes involved during orthodontic treatment will be identified.

Secondary outcome measures
Potential enzymes and genes for biomarkers will be determined (biomarkers that are involved in tooth movement i.e inflammation, bone formation, bone resorption).

Overall study start date
01/07/2007

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Both males and females, age range 14-30 years
2. Need for orthodontic treatment
3. Good general and periodontal health
4. Not pregnant
5. No use of antiinflammatory drugs, antibiotics or chlorhexidine mouthwash before and during study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patient had periodontal disease
2. Poor oral hygiene
3. Have many missing teeth prior to study

Date of first enrolment

01/07/2007

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Malaysia

Study participating centre
Orthodontic Department
Kuala Lumpur
Malaysia
50300

Sponsor information

Organisation
Ministry of Science, Technology and Innovation (Malaysia)

Sponsor details
Level 1-7
Block C4 & C5
Complex C
Pusat Pentadbiran Kerajaan Persekutuan
Putrajaya
Wilayah Persekutuan
Malaysia
62662

Sponsor type
Government

Website
http://www.mosti.gov.my

ROR
https://ror.org/012s3r374

Funder(s)

Funder type

Government

Funder Name
Ministry of Science, Technology and Innovation (Malaysia)

Alternative Name(s)
Ministry of Science, Technology and Innovation, Ministério da Ciência, Tecnologia e Inovações, Governo Federal do Brasil Ministério da Ciência, Tecnologia, Inovações e Comunicações, MCTI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Brazil

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