

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

<b>Submission date</b> 29/07/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/09/2008	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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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