

# Inflammatory markers in orthodontic treatment with clear aligners: split mouth clinical trial

<b>Submission date</b> 03/02/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/03/2017	<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

### Background and study aims

Malocclusion is a problem in the way the upper and lower teeth fit together when biting or chewing. Orthodontic treatment can be used to improve the appearance, position and function of the teeth. In the last few decades increasing numbers of adults have sought orthodontic treatment and expressed a desire for better looking and more comfortable alternatives to traditional metal braces (often referred to as “train tracks”). Clear aligners, also known as “invisible braces”, are removable retainers which apply pressure to the teeth, pushing them into the correct position. This study aims to examine the mechanisms of tooth movement by examining the make-up of the fluid found along the gum line (gingival crevicular fluid) in patients using clear aligners.

### Who can participate?

Patients aged over 18 with malocclusion requiring orthodontic treatment

### What does the study involve?

All participants are treated with clear aligners. For a period of 3 weeks one second molar (back tooth) is randomly selected for a single movement of 0.25 mm, and the contralateral (opposite) tooth is used as a control (i.e. no movement). For all the participants, before treatment and then at 1 hour, 7 days and 21 days after treatment, samples of fluid from the gum line are taken using special paper strips, which are tested in the laboratory for any chemical markers of tooth movement.

### What are the possible benefits and risks of participating?

Participants will benefit from correction of their malocclusion. There are no risks expected for those taking part in the study.

### Where is the study run from?

University of Torino (Italy)

### When is the study starting and how long is it expected to run for?

March 2014 to January 2017

Who is funding the study?  
University of Torino (Italy)

Who is the main contact?  
Dr Andrea Deregibus

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Andrea Deregibus

**Contact details**  
CIR Dental School Lingotto  
Via Nizza 230  
Turin  
Italy  
10126

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
orthomarkers2016

## Study information

**Scientific Title**  
Biochemical markers of bone metabolism during dental orthodontic treatment with clear aligners: split-mouth clinical trial

**Study objectives**  
The aim of this study is to find out if the bone remodeling markers induced by Invisalign aligners during distalization movements significantly different from sites with no orthodontic movements.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethics Board of The Health And Science City of Turin (Comitato Etico Interaziendale A.O.U. Città della Salute e della Scienza di Torino), 15/09/2016, ref: 0089263

**Study design**

Single-centre randomised split-mouth trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Malocclusion

**Interventions**

A single group of 21 patients requiring orthodontic treatment will be treated with clear aligners (Invisalign®, Align Technology, San José, CA, USA). For a period of 3 weeks one second molar will be randomly selected as study item and the contralateral will be used as control item. Using a dedicated software (ClinCheck®, Align Technology, San José, CA, USA) a single movement of 0.25 mm will be set on the first clear aligner only for the selected second molar.

Gingival Crevicular Fluid (GCF) samples will be collected using periopaper strips (Harco, Tustin, Calif). Samples will be collected at the mesiobuccal and mesiolingual sites of control and test teeth at baseline, at 1 hour, at 7 days, and 21 days after placement of the appliances. Teeth will be isolated with cotton rolls, cleaned of plaque deposits, and dried gently with air before paper strips will be applied 1 mm subgingivally for 30 seconds. The volume of the sample on the paper strips will be measured using a calibrated Periotron 8000 (Harco). The readings from the Periotron will be converted to an actual volume (microliters) by reference to the standard curve calibrated with human serum.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Cytokine concentration (interleukin 1-beta, TGF-beta, RANKL, OPG and OPN), determined from GCF samples using titration and centrifugation at baseline, 1 hour, 7 days and 21 days

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

20/03/2014

**Completion date**

30/01/2017

## Eligibility

### Key inclusion criteria

1. Age >18 years
2. Absence of systemic diseases influencing bone metabolism and/or healing process
3. Good oral hygiene (FMPS e FMBS <20%)
4. Dentoskeletal Class I malocclusion (Witts appraisal)
5. Mild crowding (mean crowding 6 mm)

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

21 patients

### Key exclusion criteria

1. Smokers
2. Have gingivitis
3. Have probing pocket depths  $\geq 4$  mm
4. Have loss of clinical attachment  $\geq 2$  mm in the selected or adjacent teeth
5. Had taken anti-inflammatory or antibiotic medications within the previous 6 months

### Date of first enrolment

20/03/2015

### Date of final enrolment

20/03/2016

## Locations

### Countries of recruitment

Italy

### Study participating centre

Dental School, Department of Orthodontics

Via Nizza 230

Turin

Italy  
10126

## Sponsor information

### Organisation

University of Torino

### Sponsor details

CIR Lingotto Dental School  
Via Nizza 230  
Turin  
Italy  
10126

### Sponsor type

University/education

### ROR

<https://ror.org/048tbm396>

## Funder(s)

### Funder type

University/education

### Funder Name

Università degli Studi di Torino

### Alternative Name(s)

University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### Location

Italy

# Results and Publications

## **Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal in 2018

## **Intention to publish date**

30/01/2018

## **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Andrea Deregibus

## **IPD sharing plan summary**

Available on request