ISRCTN32624758 https://doi.org/10.1186/ISRCTN32624758

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

Submission date
03/02/2017

Recruitment status
No longer recruiting

Registration date
09/03/2017

Overall study status
Completed

Last Edited
09/03/2017

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Smokers
2. Have gingivitis
3. Have probing pocket depths ≥4 mm
4. Have loss of clinical attachment ≥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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes