

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of RANKL and OPG release in GCF during orthodontic movement with or without Low Level Laser Therapy

#### Protocol summary

##### Summary

(1)Objective:Comparison of RANKL and OPG release in GCF during orthodontic movement with or without LLLT; (2) design: Randomized; (3) setting and conduct: just before exposure by laser , GCF samples were collected. Then, while in both sides canines were retracted by elastic retractor, one side exposed to GaAlAs laser which applied on three points of the canine root( coronal, mid and apical ) of buccal, palatal and on the distal side individually . Exposure time was 3 min on each oppoinment. The same procedure applied to the contralateral quadrant but without laser emission. Samples collected and sent to laboratory in ice- pack container for analysis of RANKL and OPG (4) Participant including criteria: public comment and were healthy periodontal, Crowding or protrusion with dental and orthodontic needs were, The right and left first premolar had been previously extracted;Participant exclusion criteria: Patient with particular systemic diseases; Patients under treatment with special medication; Smokers and patients consume alcohol; Patients that received systemic antibiotics during 6 month ago, plaque index < %40 (5) Intervention: Treatment with diod laser(6) main outcome measures: Rankl, OPG

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062228590N1**

Registration date: **2016-07-16, 1395/04/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-16, 1395/04/26

#### Registrant information

##### Name

Mahmoud Soleimani

##### Name of organization / entity

Islamic Azad University of Isfahan (Khorasgan), Dental School

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3535 4053

##### Email address

m.soleymani@khuisf.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Investigator

#### Expected recruitment start date

2015-09-23, 1394/07/01

#### Expected recruitment end date

2016-01-30, 1394/11/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of RANKL and OPG release in GCF during orthodontic movement with or without Low Level Laser Therapy

#### Public title

Comparison of inflammatory mediators release in GCF during orthodontic movement with or without Low Level Laser Therapy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: public comment and were healthy

periodontal; Crowding or protrusion with dental and orthodontic needs were; The right and left first premolar had been previously extracted Exclusion criteria: Patient with particular systemic diseases; Patients under treatment with special medication; Smokers and patients consume alcohol; Patients that received systemic antibiotics during 6 month ago; plaque index < %40

#### **Age**

From **81 years** old to **79 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **10**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Islamic Azad University of Isfahan (Khorasgan), Dental School

##### **Street address**

Islamic Azad University of Isfahan (Khorasgan), Jay Street

##### **City**

Isfahan

##### **Postal code**

#### **Approval date**

2016-05-17, 1395/02/28

#### **Ethics committee reference number**

IR.mui.rec.1395.4.22

### **Health conditions studied**

#### 1

#### **Description of health condition studied**

tooth movement

#### **ICD-10 code**

Z01.2

#### **ICD-10 code description**

Dental examination

### **Primary outcomes**

#### 1

#### **Description**

RANKL

#### **Timepoint**

0,2,7,21 days

#### **Method of measurement**

Perticular kit of elisa

#### 2

#### **Description**

OPG

#### **Timepoint**

0,2,7,21 days

#### **Method of measurement**

Perticular kit of elisa

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention: laser therapy, orthodontics treatment

#### **Category**

Treatment - Other

#### 2

#### **Description**

control: no Laser, orthodontics therapy

#### **Category**

Treatment - Other

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Islamic Azad University of Isfahan (Khorasgan), Dental School

##### **Full name of responsible person**

Mahmoud Soleimani

##### **Street address**

Islamic Azad University of Isfahan(Khorasgan), Jey Street

##### **City**

Isfahan

### **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Islamic Azad University Isfahan (Khorasgan)

**Full name of responsible person**

dr Vahid Esfahanian

**Street address**

Islamic Azad University of Isfahan (Khorasgan), Dental School

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Islamic Azad University Isfahan (Khorasgan)

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Islamic Azad University of Isfahan (Khorasgan), Dental School

**Full name of responsible person**

Mahmoud Soleimani

**Position**

Periodontics/phd

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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Islamic azad university Isfahan (Khorasgan)

**Full name of responsible person**

Mahmoud Soleimani

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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*