

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

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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

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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

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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**

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Periodontics/phd

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Web page address

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