

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of the effect of low power Diode laser therapy and placebo on the amount of Interleukin 1 beta in gingival crevicular fluid after placement separators in orthodontic patients

#### Protocol summary

##### Summary

The aim of the present study is to evaluate the effect of low level laser therapy on periodontal inflammation caused by elastomeric separators. This study is designed to be a single blind, split mouth, randomized clinical trial. Thirty 18-30 year-old orthodontic patients who do not have periodontal disease and are not under antibiotic or corticosteroid therapy are selected. Gingival status (gingival index and bleeding point index) of maxillary first molars are recorded and gingival crevicular fluid is gathered. Then, elastomeric separators are placed in mesial and distal contacts of both maxillary first molars. One molar is randomly assigned to test group and is irradiated with 980 nanometer low level laser on buccal and lingual surfaces. The contralateral molar is assigned to control group and is pretended to be irradiated with the aforementioned laser while the laser is off (placebo). One week later, the gingival status (gingival index and bleeding point index) is assessed and gingival crevicular fluid is gathered. The amount of Interleukin 1-beta in the gingival crevicular fluid is evaluated by ELISA test. Finally, the changes in the three variables are detected by statistical analysis

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011620523N2**  
Registration date: **2017-02-25, 1395/12/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-25, 1395/12/07

#### Registrant information

##### Name

Sepideh Soheilifar

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2264 2508

##### Email address

sepidehsoheilifar@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Hamedan University of Medical Sciences

#### Expected recruitment start date

2017-02-19, 1395/12/01

#### Expected recruitment end date

2017-05-19, 1396/02/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of low power Diode laser therapy and placebo on the amount of Interleukin 1 beta in gingival crevicular fluid after placement separators in orthodontic patients

#### Public title

The effect of laser therapy on gingival inflammation

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Signing informed consent; Absence of

active periodontal disease (probing depth less than 4 mm and lack of bleeding on probing in upper first molars); Absence of systemic disease. Exclusion criteria: Presence of coagulation disease; Presence of acute or chronic disease (Based on patient chart); Presence of auto-immune disease; Patients under immune-suppressive therapy or radiotherapy; Patients who consume antibiotics; Patients who consume corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs); Pregnant women. 8. Patients under periodontal treatment or prolonged consumption of chlorhexidine

#### Age

From **18 years** old to **30 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics comitee of Hamedan University of Medical Sciences

##### Street address

Shahid Fahmide street, Hamedan University of Medical Sciences

##### City

Hamedan

##### Postal code

65178-38677

#### Approval date

2017-01-14, 1395/10/25

#### Ethics committee reference number

IR.UMSHA.REC.1395.461

## Health conditions studied

### 1

#### Description of health condition studied

Gingival inflammation

#### ICD-10 code

K05

#### ICD-10 code description

Gingivitis and periodontal diseases

## Primary outcomes

### 1

#### Description

Amount of interleukin 1 beta in gingival crevicular fluid

#### Timepoint

Before placement of separator and 1 week later

#### Method of measurement

ELISA on gingival crevicular fluid

## Secondary outcomes

### 1

#### Description

Bleeding point index

#### Timepoint

Before placement of separator and 1 week later

#### Method of measurement

Occurence of bleeding during the movement of periodontal probe in gingival sulcus

### 2

#### Description

Gingival index

#### Timepoint

Before placement of separator and 1 week later

#### Method of measurement

Observation

## Intervention groups

### 1

#### Description

Intervention 1: Irradiation of Diode laser with 980 nanometer wavelength and 1.5 Watts power with pulse irradiation with pulse length of 1 millisecond and pulse distance of 1 millisecond on buccal and lingual surface of maxillary first molar

#### Category

Treatment - Other

### 2

#### Description

Irradiation of off laser with the same movement on buccal and lingual surface of maxillary first molar

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Dental Clinic of Hamedan University of Medical Sciences

**Full name of responsible person**

**Street address**

**City**

Hamedan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Said Bashirian

**Street address**

Shahid Fahmide street, Hamedan University of Medical Sciences

**City**

Hamedan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Sepideh Soheilifar

**Position**

Assistant professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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periodontics specialist- assistant professor

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## Person responsible for updating data

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**Full name of responsible person**

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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*