

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of photodynamic therapy with diode laser on reduction of gingival inflammation in fixed orthodontic patients -A randomized Clinical Trial

#### Protocol summary

##### Summary

The aim of this study is to evaluate photo dynamic therapy with diode laser( 940 nm) on reduction of gingival inflammation around orthodontic brackets.The sample consists of 60 orthodontic patients having gingival enlargement with less than one millimeter distance to bracket. Scaling will be done for all patients and excess bonding material around brackets will be removed. Plaque Index, (GI) gingival index, (BOP) bleeding on probing, Probing depth and count of porphyromonas gingivalis bacteriae will be measured two weeks after scaling. Patients will be assigned randomly into 3 groups. Group 1 receives diode laser alone, group 2 receives methylene blue solution followed by diode laser, and control group receives placebo. All measurements will be repeated 4 weeks after intervention. Since the measurments is carried out by some one other than operator and also according to the fact that this person, patients and statistical analyzer will not be informed of the group in which the patients would be placed, this research is a triple blind study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201404149085N4**

Registration date: **2015-10-31, 1394/08/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-10-31, 1394/08/09

##### Registrant information

**Name**

Amirfarhang Miresmaeili

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1823 9064

##### Email address

miresmaeili@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hamadan university of medical science

##### Expected recruitment start date

2015-10-12, 1394/07/20

##### Expected recruitment end date

2016-04-21, 1395/02/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of photodynamic therapy with diode laser on reduction of gingival inflammation in fixed orthodontic patients -A randomized Clinical Trial

##### Public title

Treatment of gum inflammation with laser

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients under orthodontic treatment ( 12-30 years old) having gingival enlargement with less than one millimeter distance to bracket Exclusion criteria: severe periodontal disease; pre existing

systemic disease; existence of calculus.

### Age

From **12 years** old to **30 years** old

### Gender

Both

### Phase

4

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

Samples were randomly divided into three groups classified by gender.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee, Hamadan University of Medical Sciences

##### Street address

Orthodontic Department, School of Dentistry, Shahid Fahmideh Street, Hamadan

##### City

Hamadan

##### Postal code

65178-38677

#### Approval date

2015-01-01, 1393/10/11

#### Ethics committee reference number

IR.UMSHA.REC.1394.329

## Health conditions studied

### 1

#### Description of health condition studied

Chronic gingivitis

#### ICD-10 code

K05.1

#### ICD-10 code description

Chronic gingivitis

## Primary outcomes

### 1

#### Description

gingival index

#### Timepoint

4 weeks after intervention

#### Method of measurement

clinical

## Secondary outcomes

### 1

#### Description

count of porphyromonas gingivalis bacteria

#### Timepoint

4 weeks after intervention

#### Method of measurement

polymerase chain reaction

## Intervention groups

### 1

#### Description

Intervention group 1: The use of diode laser for reducing gingival inflammation; Diode laser with the wave length of 940 nm and the power of 1.5 w is radiated using a fiber with the diameter of 300nm. the radiation pulse is 20 ms/s. 0.5 mm of the head of the instrument is located in gingival sulcus and radiated 3 times in 15 seconds through the buccal gingival sulcus.

#### Category

Treatment - Devices

### 2

#### Description

Control group: The use of unpowered laser as placebo.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group 2: The use of diode laser with methylene blue for reducing gingival inflammation; One drop of 1% methylene blue solution is dropped in gingival sulcus and excess of the solution is washed off with water. Then diode laser with the wave length of 940 nm and the power of 1.5 w is radiated using a fiber with the diameter of 300nm. the radiation pulse is 20 ms/s. 0.5 mm of the head of the instrument is located in gingival sulcus and radiated 3 times in 15 seconds through the buccal gingival sulcus.

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Amirfarhang Miresmaeili

**Street address**

Orthodontic Department, School of Dentistry, Shahid Fahmideh Street, Hamadan

**City**

Hamadan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research and technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

School of Medicine, Shahid Fahmideh Street,  
Hamadan

**City**

Hamadan

**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 and technology, Hamadan 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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Amirfarhang Miresmaeili

**Position**

Associate Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*