Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of photodynamic therapy with diode laser on reduction of gingival inflamation 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
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Iran (Islamic Republic of)
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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 inflamation 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

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

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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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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