

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Evaluation of the effect of co2 laser irradiation on prevention of white spot lesions around orthodontic brackets, randomized clinical trial

#### Protocol summary

##### Summary

The aim of this study is determine the effect of CO2 laser radiation on prevention of enamel white spot lesions around orthodontic brackets. For this purpose 548 upper anterior teeth will randomly be selected from orthodontic patients from 12-30 years old and divided into two groups (Test and Control). At baseline test group will be irradiated by CO2 laser and control group be irradiated by placebo laser. Immediately after treatment and 6 months later intra-oral photographs of teeth will be taken. Estimating incidence of white spot lesions, number of teeth will be counted and the span of the lesions will be computed by percent. Also, the extent of the lesions will be determined using enamel decalcification index. The data will statistically be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017052927362N2**

Registration date: **2017-07-02, 1396/04/11**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-07-02, 1396/04/11

##### Registrant information

###### Name

Majid Mahmoodzade

###### Name of organization / entity

Dental college

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0262

###### Email address

mahmoodzadeh@umsha.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Governmental (Hamadan Dentistry College)

###### Expected recruitment start date

2017-09-06, 1396/06/15

###### Expected recruitment end date

2017-11-21, 1396/08/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluation of the effect of co2 laser irradiation on prevention of white spot lesions around orthodontic brackets, randomized clinical trial

###### Public title

The effect of co2 laser on prevention of white spot lesions

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: 12-30 years old patients required orthodontic treatments; accept all of procedures and protocols of the study from the subjects; willingness to signing informed consent for disclosure of personal health information and using the data for research by anonymous. Exclusion criteria: Suffering systemic diseases or having medical history (i.e. Diabetes, HIV, or Heart disease needed to preventive antibiotic) so it could affect on oral health.

###### Age

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

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: **548**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Opposite the Mardom Park, Shahid Fahmide Boulevard, Pazhoohesh Crossroads

##### City

Hamadan

##### Postal code

654178-38741

##### Approval date

2017-05-13, 1396/02/23

##### Ethics committee reference number

IR.UMSHA.REC.1396.146

## Health conditions studied

### 1

#### Description of health condition studied

Enamel white spot lesion

#### ICD-10 code

K02.0

#### ICD-10 code description

Caries limited to enamel White spot lesions [initial caries]

## Primary outcomes

### 1

#### Description

The incidence of white spot lesions

## Timepoint

Immediately after treatment and six months after treatment

## Method of measurement

Counting teeth with white spot lesions

## Secondary outcomes

### 1

#### Description

Extent of white spot lesions

#### Timepoint

Immediately after treatment and six months after treatment

#### Method of measurement

Using Enamel Decalcification Index

### 2

#### Description

Intensity of demineralization

#### Timepoint

Immediately after treatment and six months after treatment

#### Method of measurement

Using Scoring system

## Intervention groups

### 1

#### Description

In test group, after bonding brackets, enamel surface will be exposed by by CO2 laser (DEKA Laser Technologies, Florence, Italy) with a power of 0.4 mW, wave length of 10.6 micrometer, 5 hertz, diameter 0.2 mm and pulse time 0.9 seconds. To do this, the teeth will be at distance of 5 mm from the tip of the device and person constantly will irradiate entire surface by reciprocating standard movements in 10 seconds. Laser irradiation will be performed by direct laser handpieces.

#### Category

Prevention

### 2

#### Description

In control group, after bonding the brackets, placebo laser will be irradiated.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental College

##### Full name of responsible person

Somayeh karami

**Street address**

**City**

Hamadan

2

**Recruitment center**

**Name of recruitment center**

Special Clinic of Dental college

**Full name of responsible person**

**Street address**

**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**

Saeed Bashirian

**Street address**

Opposite the Mardom Park, Shahid Fahmide  
Boulevard, Pazhoohesh Crossroads

**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**

Dentistry College, Hamadan University of Medical  
Sciences

**Full name of responsible person**

Somayeh Karami

**Position**

Professional Doctorate in Dentistry

**Other areas of specialty/work**

**Street address**

Pazhoohesh Crossroads, Shahid Fahmideh Blvd,

opposite the Mardom park

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Hamadan

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**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**

dr.karami5@gmail.com

**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*