

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 sources1**Sponsor****Name of organization / entity**Vice Chancellor for Research and technology,
Hamadan University of Medical Sciences**Full name of responsible person**

Saeed Bashirian

Street addressOpposite 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 sourceVice 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

City

Hamadan

Postal code**Phone**

+98 81 3838 1059

Fax**Email**

dr.karami5@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**Dental 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**Dental College, Opposite the Mardom Park, Shahid
Fahmide Boulevard, Pazhoohesh Crossroads**City**

Hamadan

Postal code**Phone**

+98 81 3838 1059

Fax**Email**

dr.karami5@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**Dental College, Hamadan University of Medical
Sciences**Full name of responsible person**

Somayeh karami

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Professional Doctorate in dentistry

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Hamadan

Postal code**Phone**

+98 81 3838 1059

Fax**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