Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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Professional Doctorate in Dentistry
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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