

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of CO2 laser on demineralization resistance of enamel surface around orthodontic brackets(an in vivo study)

Protocol summary

Summary

CO2 laser has been shown by many in-vitro studies to have beneficial effects on enamel surface to increase its resistance to surface demineralization. The aim of this study is to evaluate the effect of CO2 laser on demineralization resistance of enamel surface in an in-vivo caries induction model. Since the people are accustomed to use fluoridated tooth paste for their oral hygiene care which has positive preventive effect on enamel surface, in this study the beneficial effect of CO2 laser will be examined in an environment that standard oral hygiene care is in progress. In this split-mouth designed study, a minimum of 20 subjects will be enrolled. The subjects are ones who are scheduled for extraction of at least two premolars as part of their orthodontic treatment. The teeth must not have any filling or enamel defects. In each subject experimental tooth will be lased and the control tooth will receive just the guiding light. Both teeth will be subjected to caries induction during next 30 days while the patient will do the routine oral hygiene care. The teeth will be extracted and examine for surface micro-hardness and mineralization analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202209085N1**

Registration date: **2012-11-08, 1391/08/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-08, 1391/08/18

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 Sciences

Expected recruitment start date

2012-10-06, 1391/07/15

Expected recruitment end date

2013-10-06, 1392/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of CO2 laser on demineralization resistance of enamel surface around orthodontic brackets(an in vivo study)

Public title

Effect of laser on prevention of caries on teeth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Sound premolar teeth need to be extracted for orthodontic purposes on both sides

Exclusion criteria: Any restorations, enamel surface defects on each of the teeth under study or early loss of these teeth before completion of trial

Age
From **12 years** old to **35 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The candidates will receive a number according to random number table. Candidates with odds number will receive laser illumination on left premolar and the even numbers will receive it on right premolar. Since illumination on both teeth uses the guided light and laser is not visible by itself, the candidate will not be noticed which teeth had received the laser and so have no preferences on oral hygiene care according to the type of illumination.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh street

City

Hamadan

Postal code

Approval date

2012-07-07, 1391/04/17

Ethics committee reference number

D/P/16/35/9/1259

Health conditions studied

1

Description of health condition studied

Other specified diseases of hard tissues of teeth

ICD-10 code

K03.8

ICD-10 code description

Irradiated enamel

Primary outcomes

1

Description

Surface micro-hardness of enamel

Timepoint

One month after laser/ Placebo application

Method of measurement

Micro-hardness test

Secondary outcomes

1

Description

Adhesive remnant index

Timepoint

after removal of brackets

Method of measurement

Total adhesive/ Half adhesive/ No adhesive remained

Intervention groups

1

Description

Teeth illumination with guided light (No Laser) as control

Category

Placebo

2

Description

In this study a Co2 Laser device (DEKA, Italy) with wave length of 10.6um, repetition rate of 50 Hz, beam diameter of 0.2 mm and power of 0.7w will be used.

Outer surface of one premolar tooth in each patient will be swept from incisal tip to gingival margin horizontally.

Category

Prevention

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

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. Heidar Tavilani,

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh street

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

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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

