Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Oct 2026

Effect of diode laser (940nm) on postoperative sensitivity in class II composite restorations (randomized clinical trial, double blind)

Protocol summary

Study aim
The aim of this study is to determine the effect of laser on the sensitivity after composite restorations.

Design
Controlled clinical trial with parallel group. Randomized. Double-blind. Simple randomization is done for each patient by using a random number table.Thus, depending on the number if being even or odd ,the patient's left or right side is considered as the intervention group and the other side as the control group.

Settings and conduct
This study is performed on patients referred to department of restorative ward of dental faculty of Hamadan University of Medical Sciences, Iran

Participants/Inclusion and exclusion criteria
Patient should have two decayed premolar teeth at a proximal surface in right and left side of the mandible or maxilla. Teeth should have Class II caries in the mesial or distal. Teeth should be vital with no traumatic history, no cervical caries, not have any previous fillings, no periodontal disease. If the patients have used toothpaste and desensitizing solution over the past two months Or have used analgesics for 72 hours before test, Will be excluded from study.

Intervention groups
Intervention group 1:Premolar tooth on one side of the patient's mandible / maxillary jaw, which has a proximal surface decay is Considered As an intervention group. After preparing the cavity and isolation, the diode laser is applied for 30 seconds, then the adhesive is applied and the composite restoration is inserted. Intervention group 1:Premolar tooth on other side of the patient's mandible / maxillary jaw, which has a proximal surface decay is Considered as an control group. After preparing the cavity and isolation, the radiated with placebo red light for 30 seconds, then the adhesive is applied and the composite restoration is inserted.

Main outcome variables
Tooth sensitivity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190122042457N1**
Registration date: **2019-03-03, 1397/12/12**
Registration timing: **retrospective**

Last update: **2019-03-03, 1397/12/12**
Update count: **0**

Registration date
2019-03-03, 1397/12/12

Registrant information

Name
Mojgan Taheri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-15, 1397/06/24

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

Effect of diode laser (940nm) on postoperative sensitivity in class II composite restorations (randomized clinical trial, double blind)

Public title

effect of diode laser on postoperative sensitivity in composite restorations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should have two decayed premolar teeth at a proximal surface in right and left side of the mandible or maxilla. Teeth should have Class II caries in the mesial or distal. (Depth about 2 mm and less than 4 mm Bacolingual extent) Teeth should be vital with no traumatic history The teeth should not have cervical caries The teeth should not have any previous fillings. The teeth should not have a history of hypersensitivity and pulpitis The patient should not take the analgesic medication 72 hours before the test Patients should have no systemic disease that affect their periodontal and dental conditions; like Diabetes.

Exclusion criteria:

deep carious lesions on teeth that need base and liner. the patient has used toothpaste and anti-allergic solution over the past two months. The patient uses anti-inflammatory and analgesic drugs routinely. The patient has allergies to the restorative material in this study The patient has a history of neurological and psychological illnesses. The patient has very weak dental hygiene and rapid progression of caries. The patient has a history of disease or periodontal surgery in the selected tooth.

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patients have two collateral decayed premolar in disto-oclusal or mesio-oclusal surface(in maxilla or mandible). Randomly, a teeth on one side of the jaw will be considered as a control group and the collateral tooth in the same jaw will be considered as the intervention group .

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using the numerical randomization table.In a patient with two decayed premolar teeth, one is randomly designate in the intervention(laser) group and the other one allocate in the control group. The randomized table of numbers is generated by computers that customize the numbers randomly in multiple columns and rows. Examples of these tables are available on the Internet and statistical books. After get the table, the number is selected by closing the eye and inserting the finger or tip of the pen on the point of the table and moving to the right and the numbers on the path are recorded, this is repeated until 30 samples were obtained for 30 patients in the study, respectively. So if the selected number is even, the left tooth is considered as a lasers group and the right tooth is considered as the control group. And if the number is odd, the right tooth is considered as a lasers group and the left tooth is considered as the control group

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is kept blinded by receiving placebo radiation in the control tooth. The practitioner and who perform the sensitivity test are two individuals in this study. So the practitioner will carry out the intervention treatment. and the examiner blindly tests the teeth sensitivity at the follow-up sessions until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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Shahid Fahmideh St

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6517838677

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.UMSHA.REC.1397.232

Health conditions studied

1

Description of health condition studied

Tooth sensitivity

ICD-10 code
K03.89
ICD-10 code description
Other specified diseases of hard tissues of teeth

Primary outcomes

1

Description
The sensitivity of the tooth after the cold test by using the Visual analog scale
Timepoint
baseline measurement before filling teeth, one day,two week and One month after treatment.
Method of measurement
To do a cold test, a swab sprayed with cold spray and placed in the center of the teeth for 5 seconds. The patient is then asked to select 0 to 10 numbers by Visual Analogue Scale to report the severity of pain, so that he will score 10 for the most pain and choose 0 for no pain.

Secondary outcomes

1

Description
Tooth sensitivity to different stimuli
Timepoint
baseline measurement before filling teeth, one day, two week and One month after treatment.
Method of measurement
Questionnaire-The patient responds yes or no to questions about tooth susceptibility with heat and cold and sweet dishes

Intervention groups

1

Description
Control group: After cavity preparation and just before the restoration placement, the tooth in the control group is subjected to placebo irradiation from red light for 30 s. Etching and bonding procedures are done by a self-etch adhesive (Single Bond Universal, 3M ESPE ,USA) according to the manufacturer’s instructions, and then the class II cavities is restored by a resin composite (Filtek Z250 , 3M ESPE ,USA) by incremental technique. After curing, finishing is accomplished with fine-grit diamond burs (Brasseler) and Sof-Lex polishing disc system (3MESPE, St Paul,MN, USA) underwater cooling to obtain a smooth surface.
Category
Treatment - Devices

2

Description
Intervention group: . After cavity preparation and just before the restoration placement, the teeth in the experimental group is subjected to irradiation from a low-level red laser (Ezlase 940, Biolase, California, USA), emitting a wavelength of 940 nm in a continuous pulse using E4 tip. The output power of the apparatus is1W, and each tooth is irradiated for 30 s.Etching and bonding procedures were done by a self-etch adhesive (Single Bond Universal, 3M ESPE ,USA) according to the manufacturer’s instructions, and then the class II cavities is restored by a resin composite (Filtek Z250 , 3M ESPE ,USA) by incremental technique. After curing, finishing is accomplished with fine-grit diamond burs (Brasseler) and Sof-Lex polishing disc system (3MESPE, St Paul,MN, USA) underwater cooling to obtain a smooth surface.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mojgan Taheri

Position

resident of restorative dentistry

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Non-identifiable individual data, participants protocol,

study protocol, statistical analysis map, informed consent form, clinical study report, codes used in the analysis, and classification system (data dictionary) after the end of the study and after publication of the article will be published on this site.

When the data will become available and for how long

Six months after the publication of the article

To whom data/document is available

All people will have access to information

Under which criteria data/document could be used

Data is available for study by other dentists and researchers on clinical trials data with the mention of the source.

From where data/document is obtainable

To get the data, Refer to the person responsible for the study: Mojgan Taheri, email: taheri.mojgan.86@gmail.com, 00989183152146

What processes are involved for a request to access data/document

The applicant, after disclosure of the name and contact information, and the research center, should explain a summary of his research topic and how to use the data, and ensure that after using the data, the source will be mentioned.

Comments