

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Country

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	randomization table. In a patient with two decayed premolar teeth, one is randomly designated in the intervention (laser) group and the other one allocated 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 getting 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 laser group and the right tooth is considered as the control group. And if the number is odd, the right tooth is considered as a laser group and the left tooth is considered as the control group
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 Bicolingual 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.	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
Age From 20 years old to 35 years old	Ethics committees
Gender Both	1
Phase N/A	Ethics committee
Groups that have been masked • Participant • Investigator • Outcome assessor • Data analyser	Name of ethics committee کمیته اخلاق دانشگاه علوم پزشکی همدان
	Street address Shahid Fahmideh St
	City Hamadan
	Province Hamadan
	Postal code 6517838677
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-occlusal or mesio-occlusal 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 .	Approval date 2018-06-30, 1397/04/09
Randomization (investigator's opinion) Randomized	Ethics committee reference number IR.UMSHA.REC.1397.232
Randomization description Simple randomization is done using the numerical	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 is 1W, 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**

Hamadan faculty of dentistry, department of restorative dentistry

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

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Latest degree

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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