Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

Clinical assessment the effects of laser irradiation prior to restoration placement on postoperative sensitivity of Class V resin composite restorations

Protocol summary

Summary
Aim : Clinical evaluation and hypersensitivity comparison before and after treatment with or without laser application in class 5 cavities Study design : Randomized , double blind placebo controlled clinical trial Application method: A total 25 adult patients with 2 class 5 cavities were selected . The sensitivity of all teeth was examined prior to therapy (Visual analog scale was used). After cavity preparation in study group mustang laser application was done before restoration, but in control group restoration completed in routine way. Blinding process : Person who follow up the patients is totally blind for the process Inclusion criteria: Patients had at least two cervically lesions without restorations Intervention: Application of laser for evaluation of post operative sensitivity variables criteria:The sensitivity of all initially tested teeth was examined 1 day, 2 weeks ,and then 1month after treatment.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2012072810425N1**
Registration date: **2012-12-20, 1391/09/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2012-12-20, 1391/09/30

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date
2012-11-21, 1391/09/01
Expected recruitment end date
2013-01-20, 1391/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical assessment the effects of laser irradiation prior to restoration placement on postoperative sensitivity of Class V resin composite restorations

Public title
Effects of laser on postoperative sensitivity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients that inform consent before the study began , had at least two cervically lesions without restorations , were free of any painful symptoms , had good health without any systemic disease and good oral hygiene , were free of periodontal disease and without history of periodontal surgery within 3 months. Patients

were excluded from the study if they had mucosal lesion , Had local or systemic drug usage within 2 weeks , Had lichenoid lesions , were pregnant or nursing, had pacemaker and disease which affect treatment

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomized double blind placebo controlled clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad medical university

Street address
Daneshgah street

City
Mashhad

Postal code
91775-1365

Approval date
2012-09-22, 1391/07/01

Ethics committee reference number
900853

Health conditions studied

1

Description of health condition studied
Post operative sensitivity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Postoperative sensitivity

Timepoint
1 day, 2 weeks and 1 month after intervention

Method of measurement
VAS scale

Secondary outcomes

empty

Intervention groups

1

Description
Study group : KLO4 head with wavelengths of 0,63µm , and Radiation Power of 25 mW applied 1 minute from facial

Category
Placebo

2

Description
Control group: without laser treatment group

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Dental University

Full name of responsible person
Dr Hourieh Moosavi

Street address
Vakilabad Street , Park Square

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Ghoreishi Building , Daneshgah Street

City
Mashhad

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, Mashhad 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
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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