

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Evaluation of the treatment effect of low level laser Ga-Al-As on postoperative sensitivity after amalgam restorations

#### Protocol summary

##### Study aim

The purpose of the present study was to evaluate the efficacy of low level laser Ga-Al-As on improvement of postoperative hypersensitivity after amalgam restoration

##### Design

A randomized, double blinded, clinical trial(phase III) for 21 patients has been designed. Randomization is performed Based on the random numbers table obtained from [www.randomizer.org](http://www.randomizer.org).

##### Settings and conduct

This double-blind randomized clinical trial is conducted at Mashhad Dental School. Patient and evaluator of clinical signs and symptoms are not aware of the laser on or off.

##### Participants/Inclusion and exclusion criteria

Pregnancy and lactation Spontaneous pain and nocturnal teeth and a history of swelling Radiographic view with symptoms of periapical involvement (periodontal ligament dilatation, laminar destruction, and radiolucent or radiopaque lesion) The presence of faulty repairs (fractures, overhangs, orthodontics, caries) The inability to attend laser treatment sessions for any reason VAS>9 Tooth sensitivity for other reasons (gingival recession or decay or fractured tooth) Pain in other teeth other than restored tooth

##### Intervention groups

The case group: treated with Ga-Al-As laser in 4 sessions with intervals of three days. The control group: the similar condition was applied except that the device was off.

##### Main outcome variables

postoperative sensitivity after amalgam restorations

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039318N4**

Registration date: **2019-01-18, 1397/10/28**

Registration timing: **retrospective**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

##### Registration date

2019-01-18, 1397/10/28

##### Registrant information

###### Name

Ala Ghazi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 9501

###### Email address

ghazial@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-05-26, 1395/03/06

##### Actual recruitment start date

2016-01-21, 1394/11/01

##### Actual recruitment end date

2016-06-21, 1395/04/01

##### Trial completion date

2016-07-22, 1395/05/01

##### Scientific title

Evaluation of the treatment effect of low level laser Ga-Al-As on postoperative sensitivity after amalgam restorations

##### Public title

The effect of low level laser on postoperative sensitivity after amalgam restorations

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patient Satisfaction to Participate in the Study Short-term sensitivity to various stimuli such as cold, heat, sweets, etc. After amalgam restorations (from restoration to two months afterwards) Visual Analogue Scale less than 5

### Exclusion criteria:

Pregnancy and lactation Spontaneous pain and nocturnal teeth and a history of swelling Radiographic view with symptoms of periapical involvement (periodontal ligament dilatation, laminar destruction, and radiolucent or radiopaque lesion) The presence of faulty repairs (fractures, overhangs, or orthodontics, caries) The inability to attend laser treatment sessions for any reason VAS>9 Tooth sensitivity for other reasons (gingival recession or decay or fractured tooth) Pain in other teeth other than restored tooth

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: 20

Actual sample size reached: 21

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, patients are randomly divided into two groups, namely the Study and Control groups. Randomization is performed Based on the random numbers table obtained from [www.randomizer.org](http://www.randomizer.org).

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In the case group, laser therapy was performed. The control group was placed in the same conditions as the case group, and the machine beeps were simulated, but the laser device was silent.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

## Street address

Mashhad Dental School, Azadi Square, Vakilabad Blvd

## City

Mashhad

## Province

Razavi Khorasan

## Postal code

911735984

## Approval date

2016-01-13, 1394/10/23

## Ethics committee reference number

IR.mums.sd.REC.1394.85

## Health conditions studied

### 1

#### Description of health condition studied

postoperative sensitivity after amalgam restorations

#### ICD-10 code

K03.89

#### ICD-10 code description

Other specified diseases of hard tissues of teeth

## Primary outcomes

### 1

#### Description

postoperative sensitivity after amalgam restorations

#### Timepoint

immediately after treatment

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

postoperative sensitivity 3 and 6 months after amalgam restorations

#### Timepoint

3 and 6 months after treatment

#### Method of measurement

Visual Analogue Scale

## Intervention groups

### 1

#### Description

Intervention group: treated with Ga-Al-As laser (810 nm, 200 mw) in 4 sessions with intervals of three days.

#### Category

Treatment - Devices

## 2

### Description

Control group: The control group was placed in the same conditions as the case group, and the machine beeps were simulated, but the laser device was silent.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad Dental School

##### Full name of responsible person

Hamideh Sadat Mohammadipour

##### Street address

Mashhad Dental School, Azadi Square, Vakilabad Blvd

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3882 9501

##### Email

MohammadipourH@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Mashhad University of Medical Sciences, Daneshgah St.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91388-13944

##### Phone

+98 51 3882 3255

##### Email

tafaghodiM@mums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Fatemeh Asadi

#### Position

Dentist

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dentistry

#### Street address

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#### Email

asadif\_71@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Pegah Mosannen Mozaffari

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

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#### Email

mosannenp@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ala Ghazi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Mashhad Dental School, Azadi Square, Vakilabad Blvd

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3882 9501

**Email**

ghazial@mums.ac.ir

## 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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Some data including demographic properties, signs and symptoms

**When the data will become available and for how long**

Two months after article publication

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

It is permitted to use the data in other studies with reference

**From where data/document is obtainable**

mosannenp@mums.ac.ir, Dr Pegah Mosannen Mozaffari

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

Sending email to authors. the authors will send data via email during 4 weeks

**Comments**