

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A comparison between conventional pulpcap therapy with Mineral Trioxide Aggregate and laser assisted pulpcap therapy with Mineral Trioxide Aggregate in patients older than 10 who needed pulp cappings for deep caries affecting their permanent teeth

#### Protocol summary

##### Summary

This study aims at comparing two techniques of direct pulp capping with MTA alone and by means of Er:YAG laser. The study is non-randomized and single blinded, controlled with placebo, related to phase 2-3 of clinical trial. This study will be carried out on permanent teeth of patient older than 10, with deep caries but with out any signs of irreversible pulpitis. The teeth must be mature with closed apexes. Our total number of patients is 28, 14 in each group, by using this formula:  $n = (Z_{1-\alpha/2} + Z_{1-\beta})^2 (p_1(1-p_1) + p_2(1-p_2)) / (p_1 - p_2)^2$   $p_1 = 65\%$  success rate in control group  $p_2 = 100\%$  predicted success rate in intervention group  $n = 14$ . The study will be carried out on patients who needed pulp cappings for deep caries affecting their permanent teeth. The patients will be divided into two groups: 1st group using traditional technique (using MTA) for pulp cap cappings and 2nd group using laser assisted pulp capping (by means of Er:YAG laser). Patients will be asked for follow ups after 1 month, 3 months and 6 months. Vitality of the teeth will be checked during the follow up sessions by using vitality tests and x-ray radiography.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013102015078N1**  
Registration date: **2013-11-22, 1392/09/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-11-22, 1392/09/01

#### Registrant information

##### Name

Hamid Kermanshah

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21888445534

##### Email address

kermansh@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2013-11-06, 1392/08/15

#### Expected recruitment end date

2014-01-05, 1392/10/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparison between conventional pulpcap therapy with Mineral Trioxide Aggregate and laser assisted pulpcap therapy with Mineral Trioxide Aggregate in patients older than 10 who needed pulp cappings for deep caries affecting their permanent teeth

#### Public title

Laser-assisted Pulp Capping

#### Purpose

Treatment

## Inclusion/Exclusion criteria

inclusion criteria:patients older than 10 ; teeth with deep caries with less than 1 mm distance to pulp exclusion criteria:any signs of irreversible pulpitis;bruxism ; history of chemotherapy or radiotherapy

## Age

From **10 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **28**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Studies of Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

##### Approval date

2013-04-21, 1392/02/01

##### Ethics committee reference number

91-04-97-19119-81711

## Health conditions studied

### 1

#### Description of health condition studied

exposed pulps

#### ICD-10 code

K02.8

#### ICD-10 code description

Other dental caries

## Primary outcomes

### 1

#### Description

pulp vitality

#### Timepoint

1 month 3 month 6 month

#### Method of measurement

clinical vitality tests

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

using Er:YAG laser (wavelength=2940nm, long pulse. frequency= 10 Hz ,contact mode)

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran University of Medical Sciences , Dental Faculty

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for Research , Tehran University of Medical Sciences

##### Full name of responsible person

dr Yunesian

##### Street address

Central Organization of Tehran University of Medical Sciences , Keshavarz St.

##### City

Tehran

##### 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 , Tehran 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*

**City**

Tehran

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**Full name of responsible person**

Hamid Kermanshah

**Position**

Assisted Professor

**Other areas of specialty/work****Street address**

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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*