

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

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Name of organization / entity

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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

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

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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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Assisted Professor

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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