

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical and radiographic assessment of the success of pulpotomy of primary molars with diode laser and three different capping agents

Protocol summary

Study aim

this study aimed to assess the clinical and radiographic success of pulpotomy with diode laser and three different remineralizing capping agents.

Design

This split-mouth double-blind randomized clinical trial evaluated 30 children between 3-8 years

Settings and conduct

This split-mouth double-blind randomized clinical trial evaluated 30 children between 3-8 years presenting to the Pediatric Dentistry Department of School of Dentistry, Shahed University of Medical Sciences

Participants/Inclusion and exclusion criteria

The clinical and radiographic inclusion criteria were: children requiring pulpotomy for 3 primary molars due to severe caries, with no swelling or fistula, no sensitivity to percussion, and no mobility or sinus tract. Also, the teeth had to be vital and restorable with stainless steel crowns (SSCs). no periapical or furcation radiolucency, no internal/external root resorption, no periodontal ligament widening, and physiological root resorption not exceeding more than one-third of the root length

Intervention groups

The teeth were randomly divided into three groups. diode laser with red light was used after hemostasis. The tip of the output nozzle was positioned over the pulp chamber with 2 mm distance from the canal orifice (non-contact mode), and laser was irradiated for 2 min and 15 s at 4 J/cm² energy density. The pulp chamber was then capped with CH in group 1, MTA in group 2, CEM in group 3 followed by reinforced zinc oxide eugenol (ZOE) and the tooth received a SSC.

Main outcome variables

The clinical and radiographic success rate in pulpotomized primary molars

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200328046884N1**

Registration date: **2021-06-29, 1400/04/08**

Registration timing: **retrospective**

Last update: **2021-06-29, 1400/04/08**

Update count: **0**

Registration date

2021-06-29, 1400/04/08

Registrant information

Name

Fateme Taghizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5542 4577

Email address

taghizadefateme@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2017-12-06, 1396/09/15

Actual recruitment start date

2017-10-22, 1396/07/30

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

2020-12-20, 1399/09/30

Scientific title

Clinical and radiographic assessment of the success of pulpotomy of primary molars with diode laser and three different capping agents

Public title

mineral trioxide aggregate(MTA), calcium-enriched mixture (CEM) cement and Calcium hydroxide in pulpotomized primary molar with laser

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

mental and physical health

Exclusion criteria:

uncooperative child or parents

Age

From **3 years** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **3**

three primary molar per person

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **3**

three primary molar per person

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahed University

Street address

Persian Gulf Highway (Tehran - Qom), facing the holy shrine Imam Khomeini, Shahed University

City

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Province

Tehran

Postal code

3319118651

Approval date

2018-01-08, 1396/10/18

Ethics committee reference number

IR.Shahed.REC.1396.91

Health conditions studied**1****Description of health condition studied**

primary molar pulpotomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Clinical and radiographic assessment of the success of pulpotomy of primary molars

Timepoint

The teeth were evaluated clinically and radiographically before treatment and after 9, 18 and 36 months by a pediatric dentist who was blinded

Method of measurement

Zurn and Seale scale

Secondary outcomes

empty

Intervention groups**1****Description****Category**

empty

2**Description**

Intervention group: In group 1, diode laser with red light (Mustang 2000; Russia), KLO4 output nozzle with 0.5 cm² cross-sectional area, 30 mW maximum power, and 632 nm continuous-wave mode was used after hemostasis. The tip of the output nozzle was positioned over the pulp chamber with 2 mm distance from the canal orifice (non-contact mode), and laser was irradiated for 2 min and 15 s at 4 J/cm² energy density. The pulp chamber was then capped with CH followed by reinforced zinc oxide eugenol (ZOE) and the tooth received a SSC. In group 2, laser was irradiated after hemostasis as explained for group 1, and then CEM cement (Bionique Dent, Tehran, Iran) was applied over the pump chamber followed by reinforced ZOE and the tooth received a SSC.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Dentistry Department of School of Dentistry,
Shahed University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

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

Shahed University

Proportion provided by this source

5

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**

Shahed University

Full name of responsible person

Roza Haghgoo

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available