Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

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+98 31 5542 4577

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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
Tehran
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
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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