

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of clinical and radiographic outcome between diode980nanometer laser pulpotomy and formocresol pulpotomy in primary molars

Protocol summary

Study aim

Comparison of clinical and radiographic outcome between diode980nanometer laser pulpotomy and formocresol pulpotomy in primary molar teeth during 6 and 12 months follow up.

Design

In this research, a total of 22 healthy children with an average age of 2-10 years-old had two primary molars in two quadrants need to be pulpotomy were selected and teeth were randomly divided in two control and intervention groups

Settings and conduct

A pulpotomy technique is performed by a pediatrician in a private clinic. In order to complete the pulpotomy, the selected teeth of each patient should be randomly divided two group. In group one, a sterilized cotton pad with formocresol is placed on canal orifices for 5 minutes, in group two the diode980nm laser is radiated into canal orifice using a specialized handpiece for 5 seconds, and after pulp color changed, pulp chamber is gently filled by 2 mm of reinforced ZOE and then the tooth is restored. Results of clinical evaluations and periapical radiographies of the 6th and 12th months will be recorded and compared.

Participants/Inclusion and exclusion criteria

- 1) Selected children should not have high-risk and underlying disease or contraindications to pulp treatment
- 2) Children with an average age of 2 to 10 years who having at least two primary molar teeth in two quadrants need to be pulpotomy
- 3) Teeth should not have necrotic pulp, swelling, mobility, spontaneous pain, sinus tract, fistula or abscess
- 4) Absence radiographic symptoms such as internal and external root resorption, pathologic lesions in the furcation and periapical area, pulp stone, PDL widening, loss of lamina dura
- 5) Pulp exposure during caries removal
- 6) Can be restored with amalgam or SSC

Intervention groups

In one intervention group, diode 980nms laser and in the other intervention group, formocresol is used

Main outcome variables

Clinical success; Radiographic success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210311050676N1**

Registration date: **2021-03-21, 1400/01/01**

Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**

Update count: **1**

Registration date

2021-03-21, 1400/01/01

Registrant information

Name

Amene Taghdisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

ataghdisi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-25, 1400/01/05

Expected recruitment end date

2021-03-28, 1400/01/08

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of clinical and radiographic outcome between diode 980 nm laser pulpotomy and formocresol pulpotomy in primary molars

Public title
Evaluation of the effect of Diode 980 nm laser on the success of deciduous teeth pulpotomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Selected children should not have high-risk and underlying disease or contraindications to pulp treatment Children with an average age of 2 to 10 years who having at least two primary molar teeth in two quadrants need to be pulpotomy Teeth should not have necrotic pulp, swelling, mobility, spontaneous pain, sinus tract, fistula or abscess Absence radiographic symptoms such as internal and external root resorption, pathologic lesions in the furcation and periapical area, pulp stone, PDL widening, loss of lamina dura Pulp exposure during caries removal Can be restored with amalgam or SSC
Exclusion criteria:
primary molar teeth with superficial caries Teeth that fall out soon

Age
From **2 years** old to **10 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **22**
More than 1 sample in each individual
Number of samples in each individual: **2**
Two

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants don't know which teeth have been treated with laser and which teeth have been treated with formocresol The doctor who performs treatment, know which teeth have been treated with laser and which teeth have been treated with formocresol Responsible for data collection and analysis don't know which teeth

have been treated with laser and which teeth have been treated with formocresol

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan university of medical sciences

Street address

Kashan University of Medical Sciences, Kashan, IRAN

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2021-03-06, 1399/12/16

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.013

Health conditions studied

1

Description of health condition studied

Vital pulp therapy in primary teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Clinical success rate of treatment

Timepoint

6th and 12th month

Method of measurement

clinical observation of teeth

2

Description

Radiographical success rate of treatment

Timepoint

6th and 12th month

Method of measurement

periapical radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pulpotomy with formocresol, In this group, cotton soaked in diluted formocresol (1: 5) of master dent is placed on each orifice for 5 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: pulpotomy with DIODE980nm laser, In this group, pulpotomy with diode 980 nm laser from company nu smile simpler 2, at a distance of 1 mm from the orifice is continuously irradiated by a fiber optic with a diameter of 320 µm for 5 seconds and applied non-contact on each orifice, which if coagulation is observed Blood decreases this time.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Private office

Full name of responsible person

Dr Amene Tghdisi

Street address

Kashan, Beheshti Street, Goli Alley

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Kashan

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8715973474

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Faeze Mirjalili

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr Amene Taghdisi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric dentist

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Amene Tghdisi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric dentist

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Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Fahimeh Ghasemi

Position

Dentistry student

Latest degree

A Level or less

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