Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effect of pulpotomized primary molars using CEM cement, Formocresol , MTA and Laser

Protocol summary

Summary

Pulpotomy is one of the most common treatments for deciduice teeth used by dentists particularly pediatrists . This research aims to compare CEM (introduced recently by Dr Asgary and colleagues) with other materials and techniques such as MTA , formocresol and laser use in pulpotomy of deciduice teeth. Nowadays , the most commonly used material for deciduice teeth pulpotomy treatment is formocresol .further investigations are needed on laser therapy of deciduice teeth .Some researches indicate relative superiority of CEM over MTA . in this randomized clinical trial study , 120 pair of first and second deciduice molar teeth who prescribed pulpotomy treatment of Patients aged 5-8 years old are divided into four test groups. In group one, a cotton ball soaked in formocresol is placed on canal orifices for 5 minutes , and after its color change ,pulp chamber is gently filled by 2 mm of reinforced ZOE . In group two and three, pulp chamber is filled gently by 2mm MTA and CEM, respectively .In these 3 groups ,SDI amalgam is used as tooth restoration . In group 4 ,laser is radiated into canal orifice using a specialized handpiece After clinical examinations and taking radiography in the same session ,patients will be reevaluated clinically and radiographically after 6 and 12 months.Results of clinical evaluations and priapical radiographies of the first session , 6th and 12th months will be recorded and compared.

General information

Acronym

vpt

IRCT registration information

IRCT registration number: **IRCT138706241191N2**
Registration date: **2008-10-07, 1387/07/16**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2008-10-07, 1387/07/16

Registrant information

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Saeed Asgary
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Iranian Center for Endodontic Research
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Recruitment status

Recruitment complete

Funding source

iran center of dental research and iran center of endodontics research

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2009-05-20, 1388/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of pulpotomized primary molars using CEM cement, Formocresol , MTA and Laser

Public title

vital pulp therapy in primary teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Patients with good cooperation and no systemic disorder , developmental deficiencies , mental retardation nor physical disability which hampers their cooperation and no medication therapy were selected for this study. And they select based on following clinical and radiographic criteria: Clinical criteria: 1-lack of spontaneously pain 2-lack of obvious mobility 3- lack of sensitivity to percussion 4-lack of swelling and fistula and no sign of necrosis and abscess or redness of gingival adjacent to apex area 5-lack of extensive irrepairable coronal decay 6- lack of regional lymphodenopathy 7- lack of periodontal pocket Radiographic criteria: 1-extention of decay to pulp region without any of above clinical signs and symptoms 2- lack of internal and external resorption 3-lack of calcific degeneresence pulp or pulp stone 4-lack of periapical or furcation radiolucency.

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran Center for Dental Research

Street address

5th floor , shahid beheshti dental school, Evin

City

Tehran

Postal code

19839613113

Approval date

2008-06-10, 1387/03/21

Ethics committee reference number

8719

Health conditions studied

1

Description of health condition studied

vital pulp therapy of primary molars

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

presence of pain

Timepoint

next day

Method of measurement

Yes or No

Secondary outcomes

1

Description

radiographical success rate of treatment

Timepoint

first secion,6th and 12th month

Method of measurement

priapical radiography

Intervention groups

1

Description

pulpotomy with MTA(mineral trioxide aggregate)

Category

empty

2

Description

pulpotomy with CEM(new endodontic cement)

Category

empty

3

Description

pulpotomy with formocresol

Category

empty

4

Description

pulpotomy with laser

Category

empty

Recruitment centers

1

Recruitment center
Name of recruitment center
dental school of shahid beheshti university
Full name of responsible person
Dr.Beheshteh Malek afzali
Street address
shahid beheshti dental school, Evin ,Tehran
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2

Recruitment center
Name of recruitment center
dental school of shahed university
Full name of responsible person
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shahed dental shool,Italia st. Keshavarz Blvd,Tehran
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3

Recruitment center
Name of recruitment center
dental school of mashhad university
Full name of responsible person
Dr alireza sarraf
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
iran center of endodontics research center
Full name of responsible person
Dr.saeed asgary
Street address
5th floor , shahid beheshti dental school, Evin ,Tehran
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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
iran center of endodontics research center
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
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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
iran center of dental research
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
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Country of origin
Type of organization providing the funding
empty

3

Sponsor
Name of organization / entity
dental school of shahed university
Full name of responsible person
Dr majid mehran
Street address
pediatrics department,dental school of shahed university,Tehran
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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
dental school of shahed university
Proportion provided by this source
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

4

Sponsor
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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
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Proportion provided by this source
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

Person responsible for general inquiries

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Person responsible for scientific inquiries

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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