Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of clinical and radiographic success rates of Pulpotomy in primary molars using formocresol, Portland cement and NeoMTA Plus: a double-blind randomized clinical trial

Protocol summary

Study aim
Comparison of clinical and radiographic success rates of Pulpotomy in primary molars using formocresol, Portland cement and NeoMTA Plus: a double-blind randomized clinical trial

Design
A Clinical trial with control, interventional, blind, and randomized groups with a parallel group design of 96 primary molar teeth

Settings and conduct
This study was performed on 96 primary molars in healthy children aged 3 to 9 years who had referred to the pediatric dental office for dental treatment. Treatment with three substances such as formocrozole, Portland cement and NeoMTA Plus was performed by a pediatric dentist in a pediatric dental office. In this study, follow-up evaluations were performed in radiographic and clinical aspects at least 12 months after calibration. , Two researchers who are not aware of the type of treatment comment on radiographic criteria. In case of disagreement between them, a single conclusion will be reached by discussing the disputed samples.

Participants/Inclusion and exclusion criteria
Pulp exposure due to caries؛ No pathologic mobility؛ No history of spontaneous pain؛ No sinus tracts, abscess or swelling؛ Restorable teeth with stainless-steel crown؛ Hemostasis could be easily achievable؛ No internal or pathologic external root resorption؛ No interradicular or periapical radiolucency

Intervention groups
Group 1: Portland Cement ؛ Group 2: NeoMTA Plus

Main outcome variables
Mutation and cytogenic effect of formocresol

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180521039763N5**
Registration date: **2022-03-14, 1400/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-14, 1400/12/23**
Update count: **0**

Registration date
2022-03-14, 1400/12/23

Registrant information

Name
Fatemeh Jahanimoghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3211 8071

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jahanimoghadam@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-24, 1400/12/05

Expected recruitment end date
2022-08-27, 1401/06/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of clinical and radiographic success rates of

Pulpotomy in primary molars using formocresol, Portland cement and NeoMTA Plus: a double-blind randomized clinical trial

Public title

Comparison of clinical and radiographic success rates of Pulpotomy in primary molars using formocresol, Portland cement and NeoMTA Plus: a double-blind randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pulp exposure due to caries No pathologic mobility No pain in percussion No history of night pain No sinus tracts, abscess or swelling Restorable teeth with ssc Hemostasis could be easily achievable No internal or pathologic external root resorption No interradicular or periapical radiolucency and Periodontal ligament widening

Exclusion criteria:

Existence of any systemic disease such as leukemia that the child can not be treated with pulp therapy internal or pathologic external root resorption Periodontal ligament widening interradicular or periapical radiolucency If more than two thirds of the root length has undergone physiological resorption Blockage of the pulp canals

Age

From **3 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Given that external factors, such as age and/or gender, are not affected by the outcome (clinical and radiographic success rate) there is no need for advanced randomization such as minimization. In addition, a therapist will perform all pulpotomies to eliminate the role of the therapist.Therefore, individuals in this study, using simple randomization and random numbers are entered into three groups of study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Follow up evaluations are carried out by two researchers who are not aware of the type of treatment and they will comment on radiographic criteria. The statistician is not aware of the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Shafa Ave

City

kerman

Province

Kerman

Postal code

7618759689

Approval date

2021-07-13, 1400/04/22

Ethics committee reference number

IR.KMU.REC.1400.223

Health conditions studied

1

Description of health condition studied

pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Mutation and cytogenetic formocresol

Timepoint

12 month later

Method of measurement

Through clinical and radiographic evaluation and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Cotton pellet impregnated with formocresol (sultan, USA) is placed on the pulp for 5 minutes

Category

Treatment - Drugs

2

Description
Intervention group: 1: After pulp tissue homeostasis, Portland cement (Votoran; SãoPaulo, SP, Brazil) is mixed according to the manufacturer's instructions and placed in thepulp chamber. 2: After pulp tissue homeostasis, NeoMTA Plus material (Avalon Biomed Inc. (Bradenton, FL, USA) is combined according to the manufacturer's instructions and will be placed in the pulp chamber .

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric dental office
Full name of responsible person
Pouya Karimipour Fard
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2

Recruitment center
Name of recruitment center
Faculty of Dentistry
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Pouya Karimipour Fard
Position
Doctor of dental surgery student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only a portion of the data is shared, such as the original outcome information.

When the data will become available and for how long
Start the access period, 6 months after printing the results.

To whom data/document is available
Only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used
For researchers

From where data/document is obtainable
pouyakm1996@gmail.com

What processes are involved for a request to access data/document
1 month

Comments