

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 formocresol, 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)

Phone

+98 34 3211 8071

Email address

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 <i>No information</i> 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 <u>1</u> 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 <u>1</u> Description of health condition studied pulpitis ICD-10 code K04.0 ICD-10 code description Pulpitis Primary outcomes <u>1</u> Description Mutation and cytogenetic formocresol Timepoint 12 month later Method of measurement Through clinical and radiographic evaluation and questionnaire Secondary outcomes empty Intervention groups <u>1</u> Description Control group: Cotton pellet impregnated with formocresol (sultan, USA) is placed on the pulp for 5 minutes Category Treatment - Drugs
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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 the pulp 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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Recruitment center

Name of recruitment center

Faculty of Dentistry

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Sponsors / Funding sources

1

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

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

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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