Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of clinical and radiographic success rate of pulpotomy in primary molars using Biodentine, Endo repair and Formocresol: A double blind randomized clinical trial

Protocol summary

Study aim
Comparison of clinical and radiographic success rate of pulpotomy in primary molars using Biodentine, Endo repair and Formocresol: A double blind randomized clinical trial

Design
A Clinical trial with control, interventional, blind, and randomized groups with a parallel group design of 105 patients

Settings and conduct
This project will be carried out in the Department of Pediatrics of the Kerman School of Dentistry. Before treatment, adequate explanations will be given on the clinical approach and treatment logic as well as possible risks to the parents. Pulpotomy treatment of all teeth will be done by a specialized dentistry assistant and supervised by the relevant teacher. Follow up evaluations are carried out by two researchers who are not familiar with the type of treatment and will comment on radiographic criteria.

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 ssc, Hemostasis could be easily achievable, No internal or pathologic external root resorption, No interradicular or periapical radiolucency

Intervention groups
group1 : Biodentine , group2: Endo repair

Main outcome variables
Mutation and cytogenic effect of formocresol

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180521039763N2**
Registration date: **2019-05-09, 1398/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-09, 1398/02/19**
Update count: **0**

Registration date
2019-05-09, 1398/02/19

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
2018-10-22, 1397/07/30

Expected recruitment end date
2019-09-21, 1398/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of clinical and radiographic success rate of pulpotomy in primary molars using Biodentine, Endo repair and Formocresol: A double blind randomized clinical trial

Public title
Comparison of clinical and radiographic success rate of pulpotomy in primary molars using Biodentine, Endo repair and Formocresol: A double blind randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pulp exposure due to caries No pathologic mobility No history of spontaneous 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
Exclusion criteria:
Age
From **3 years** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**
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
2018-10-07, 1397/07/15
Ethics committee reference number
IR.KMU.REC.1397.324

Health conditions studied

1

Description of health condition studied
Pulpitis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mutation and cytogenetic formocresol
Timepoint
0 , 6 and 12 months 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, the Biodentine substance (Septodont, Saint-Maur-des-Fosses, France) is placed into the pulp chamber according to the manufacturer's instructions. 2: After the pulp tissue

homeostasis, the material Endo repair (HOFFMANN'S, Germany) 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
Faculty of Dentistry
Full name of responsible person
Farzane Jalali
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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
Farzane Jalali
Position
Resident
Latest degree
Specialist
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
fznjalali@gmail.com
What processes are involved for a request to access data/document
1 month
Comments