Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative evaluation of the success rate of applying formocresol, 3Mixtatin and Mineral trioxide aggregatein pulpotomy of primary molars

Protocol summary

Summary

The rationale for pulpotomy of primary molars is based on the assumption that inflammation is limited to the coronal portion of the dental pulp and that the radicular pulp has the potential to heal. Since 1950, formocresol (FC) has been widely used as a pulp dressing material for pulpotomy of primary molars. However, many concerns have been raised about the potential mutagenicity and carcinogenicity of FC in humans and therefore alternative pulpotomy agents have been proposed. In the present study, we suggest using 3Mixtatin, a combination of 3Mix (combination of metronidazole, minocycline, and ciprofloxacin) and Simvastatin, as a pulpotomy material. This combination, 3Mixtatin, will be applied with the aim of suppressing bacteria, preventing the pulp inflammation and inducing hard tissue formation. After local anesthesia, isolation and removing caries, following removal of the coronal pulp and hemostasis, the pulp stumps will be covered with 3Mixtatin in group B and Mineral trioxide aggregate (MTA) in group C. In the control group, FC will be placed with a cotton pellet over the pulp stumps for 5 minutes and removed. The pulp stumps will then be covered by reinforcezinc oxide eugenol (ZOE) paste. All of the treated teeth will subsequently be restored with amalgam and radiography will be taken. The teeth will be followed up 3 months after treatment. In follow up appointment, teeth will be evaluated radiographically and clinically with two examiners who are blind to the experiment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902203893N2**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

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Naser Aasl Aminabadi
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Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the success rate of applying formocresol, 3Mixtatin and Mineral trioxide aggregatein pulpotomy of primary molars

Public title

Comparative evaluation of the success rate of applying formocresol, 3Mixtatin and Mineral trioxide aggregatein pulpotomy of primary molars

Purpose
Treatment
Inclusion/Exclusion criteria
Procedure, possible risks, as well as possible benefits will be thoroughly explained to the parents of the patients aged 3-6 years old and a written informed consent will be taken. Teeth have to had appropriate clinical and radiographic sign and symptoms: 1. Caries primary molars with vital pulp 2. No history of spontaneous 3. No swelling (of pulpal origin) 4. No fistula 5. No pathological tooth mobility 6. No pathologic external root resorption 7. No pathological internal root resorption 8. No periapical or interradicular radiolucency 9. No pulp calcifications 10. No excessive bleeding from the amputated radicular stumps. 11. No history of nocturnal pain 12. No tenderness to percussion or palpation 13. Normal gingival and periodontal condition 14. Absence of periapical or furcal radiolucencies 15. Complete physical and mental health 16. Available to be restored by amalgam or SSC 17. Availability for 3 months follow up
Age
From **3 years** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **93**
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
Tabriz Institutional Review Board
Street address
Tabriz University of Medical Sciences
City
Tabriz
Postal code
Approval date
2016-02-15, 1394/11/26
Ethics committee reference number
IR.TBZMED.REC.1395.47

Health conditions studied

1

Description of health condition studied
Irreversible Pulpitis
ICD-10 code
K04.0
ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Dental hard tissue formation
Timepoint
Before and 3 months after intervention
Method of measurement
Radiography

Secondary outcomes

1

Description
Pain
Timepoint
Before and 3 months after intervention
Method of measurement
Question and palpation

2

Description
Mobility
Timepoint
Before and 3 months after intervention
Method of measurement
Palpation

3

Description
Bone radiographic repair
Timepoint
Before and 3 months after intervention
Method of measurement
Radiography

Intervention groups

1

Description
in Formocresol group , Following the removal of caries and exposure of the pulp, the coronal pulp tissue was removed.A sterile cotton pellet soaked in sterile saline, after cotton pellet soaked in formocresol was placed on the remaining pulp tissue.The cotton pellet was removed from the cavity, a layer of reinforced-zinc oxide eugenol

was then placed on the root pulp and the tooth was restored with amalgam

Category

Treatment - Drugs

2

Description

in 3Mixtatin group, Following the removal of caries and exposure of the pulp, the coronal pulp tissue was removed.A sterile cotton pellet soaked in sterile saline. The cotton pellet was removed from the cavity, a layer of 3mixtatin(were mixed with normal saline) was then placed on the root pulp and the tooth was restored with amalgam.

Category

Treatment - Drugs

3

Description

in Mineral trioxide aggregate group (MTA), Following the removal of caries and exposure of the pulp, the coronal pulp tissue was removed.A sterile cotton pellet soaked in sterile saline. The cotton pellet was removed from the cavity, a layer of MTA was then placed on the root pulp and the tooth was restored with amalgam.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry

Full name of responsible person

Dr. Vajihe Alavi

Street address

Department of Pediatric Dentisry, Tabria Faculty of Dentistry

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz Faculty of Dentistry

Full name of responsible person

Dr. Samiei

Street address

Dean for Research, Tabriz Faculty of Dentistry

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz Faculty of Dentistry

Proportion provided by this source

100

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

Contact

Name of organization / entity

Tabriz Faculty of Dentistry

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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