

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative evaluation of the success rate of applying formocresol, 3Mixtatin and Mineral trioxide aggregate in 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 reinforce zinc 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

Name

Naser Aasl Aminabadi

Name of organization / entity

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 aggregate in pulpotomy of primary molars

Public title

Comparative evaluation of the success rate of applying formocresol, 3Mixtatin and Mineral trioxide aggregate in 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 3Mmixtatin 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 Dentistry, Tabriz 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