

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

###### Country

Iran (Islamic Republic of)

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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**

Tabriz

**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**

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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**

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**

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## Web page address

## 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*