

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of 3Mixtatin and MTA (Mineral Trioxide Aggregate) in direct pulp capping of primary molar teeth. A Randomized controlled clinical Trial

Protocol summary

Summary

the aim of this study is to compare clinical and radiographic success rates of direct pulp capping (DPC) in primary molars teeth using Mineral Aggregate trioxide (MTA) and a mixture of Simvastatin with three antibiotics (3mixtatin) as a novel endodontic biomaterial. This randomized controlled clinical trial carried on 53 children 4-9 years old that had at least one deep decayed primary molars teeth and the teeth had no spontaneous pain, swelling, fistula, sinus tract, sensitivity to percussion and palpation. The patient did not have systemic diseases. Every tooth, after local anesthesia, was isolated with rubber dam and caries was removed. The bleeding of pin point exposure was controlled and one of two materials was randomly applied on the pin point, then the tooth restored with amalgam. The patients were recalled every 2, 6 and 12 months to evaluate clinical and radiographic success.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042121891N1**
Registration date: **2015-06-16, 1394/03/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name

Ebrahim Najafpour

Name of organization / entity

Faculty of Dentistry, Tabriz University of Medical

Science

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-10-21, 1393/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 3Mixtatin and MTA (Mineral Trioxide Aggregate) in direct pulp capping of primary molar teeth. A Randomized controlled clinical Trial

Public title

Comparison of antibiotic regimens in repair of primary caries in molar teeth.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Complete physical and mental health without any confounding medical history; Teeth deemed restorable with amalgam; No pathology of the succedaneous permanent teeth follicles; Clinical and Radiographic normal conditions.

Age

From **4 years** old to **9 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Committee for Ethics in Research on Humans at Tabriz
University of Medical Science

Street address

Tabriz University of Medical Science, Golgasht Ave,
Tabriz

City

Tabriz

Postal code**Approval date**

2015-06-13, 1394/03/23

Ethics committee reference number

TBZMED.REC.1394.209

Health conditions studied**1****Description of health condition studied**

Primary tooth pulp exposure

ICD-10 code

K04

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes**1****Description**

pain

Timepoint

before and after intervention.

Method of measurement

clinical examination

2**Description**

tenderness to percussion

Timepoint

before and after intervention.

Method of measurement

clinical examination

3**Description**

mobility

Timepoint

before and after intervention.

Method of measurement

clinical examination

4**Description**

radiolucency

Timepoint

before and after intervention.

Method of measurement

radiographic examination

5**Description**

internal resorption

Timepoint

before and after intervention.

Method of measurement

radiographic examination

Secondary outcomes

empty

Intervention groups**1****Description**

test :applying 3mixtatin(3 antibiotics with Simvastatin)

Category

Treatment - Drugs

2**Description**

control :applying MTA

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Science

Full name of responsible person

Dr Soheil Satrab

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Faculty of Dentistry, Tabriz University of Medical Science, Golgasht Ave, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Dr Naser Asl Aminabadi

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Faculty of Dentistry, Tabriz University of Medical Science, Golgasht Ave, Tabriz, Iran

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Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Science

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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Full name of responsible person

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Position

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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