Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
Committe 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 intervation.
Method of measurement
clinical examination

2

Description
tenderness to percussion
Timepoint
before and after intervation.
Method of measurement
clinical examination

3

Description
mobility
Timepoint
before and after intervation.
Method of measurement
clinical examination

4

Description
radiolucency
Timepoint
before and after intervation.
Method of measurement
radiographic examination

5

Description
internal resorption
Timepoint
before and after intervation.
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

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

City
Tabriz

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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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

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Other areas of specialty/work

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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