

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Effect of 3Mixtatin to preserve primary teeth: a randomized clinical trial

Protocol summary

Summary

The aim of the present study was to assess the effect of a combination of three antibiotics and simvastatin (3Mixtatin) on the repair in hopeless primary molars. In this randomized clinical trial, 80 teeth from 65 healthy children aged 3–6 years with interradicular or periapical root resorption and/or perforation in primary molars were treated with either 3Mixtatin or MTA before restoration. The subjects were followed up clinically and radiographically 4, 6 and 12 months after pulp treatment to evaluate and compare the healing process. The data were compared using chi-square test at a significance level of 0.05. At the end of 12 months in 3Mixtatin group, 32 (96.9%) teeth revealed no clinical signs or symptoms with arrested resorption progress radiographically. In MTA group, clinical signs and symptoms including pain, mobility and sinus tract were seen in 18 (47.3%) teeth with cessation of root/interradicular radiolucency in 8 (21.0%) teeth but no bone repair. Healing with no inflammation and hard tissue formation occurred more successfully following 3Mixtatin treatment compared with treatment with MTA. This finding can have direct implications for preservation of hopeless primary teeth with perforation or root resorption.

General information

Acronym

MTA : mineral trioxide aggregate 3mixtatin : 3mix + simvastatin 3mix: A combination of metronid

IRCT registration information

IRCT registration number: **IRCT2013071714031N1**
Registration date: **2013-10-14, 1392/07/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-14, 1392/07/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-10-19, 1391/07/28

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 3Mixtatin to preserve primary teeth: a randomized clinical trial

Public title

Comparison of antibiotic regimens in repair of primary molars of 3 to 6 years old children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: •Complete physical and mental health without any confounding medical history. •Teeth deemed restorable with a stainless steel crown, amalgam or composite restoration. •No pathology of the succedaneous permanent teeth follicles. •Interradicular

perforation and/or root resorption in 1/3 coronal of root with adequate bone support.

Age

From **3 years** old to **6 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

Tabriz University of Medical Sciences

Street address

Tabriz Dental Faculty, Golgasht St.

City

Tabriz

Postal code

Approval date

2012-09-17, 1391/06/27

Ethics committee reference number

9272

Health conditions studied

1

Description of health condition studied

Perforation and resorption

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Perforation and resorption

Timepoint

Before and after dental intervention

Method of measurement

Radiographical and clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

3mixtatin

Category

Treatment - Drugs

2

Description

control: applying MTA

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Dental Faculty

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Naser Asl Aminabadi

Street address

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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 University of Medical Sciences

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***Phone**

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Postal code**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*