

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of Clinical and Radiographic success rate of Lesion Sterilization and Tissue Repair in non vital primary molars : a Clinical Trial

#### Protocol summary

##### Summary

Objectives :Evaluation of Clinical and Radiographic success rate of Lesion Sterilization and Tissue Repair in non vital primary molars Design : Single blind , Randomized , with control Method:Clinical and radiographic signs of samples were recorded before intervention.Conventional pulpectomy was done for 25 teeth(control group). A mixture of 3mix Ciprofloxacin, Metronidazole and Minocycline was placed on the floor of the pulp chamber covering the root canal orifices(25 teeth). All the teeth were restored with stainless steel crowns. Post operative clinical and radiographic evaluation was done after 2,6 and 12 months. Participants: Healthy children, visiting Dept. of Pediatric ,Mashhad dental school, aged between 4 - 8 years Inclusion criteria : Healthy children who were having 50 infected primary teeth Exclusion criteria:children with systemic and immunosuppressed diseases Intervention:using the 3 Mix Antibiotic paste on the floor of the pulp chamber Main outcome variables :No clinical symptoms such as pain on percussion, history of swelling, or sinus tracts, remission of periradicular radiolucent lesion- no progress of lesion- no internal and external resorption

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013112615558N1**  
Registration date: **2016-07-03, 1395/04/13**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-03, 1395/04/13

#### Registrant information

##### Name

Homa Noorollahian

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3766 5343

##### Email address

noorollahianh@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research of Mashhad university of medical sciences

#### Expected recruitment start date

2016-04-20, 1395/02/01

#### Expected recruitment end date

2016-06-04, 1395/03/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of Clinical and Radiographic success rate of Lesion Sterilization and Tissue Repair in non vital primary molars : a Clinical Trial

#### Public title

root canal therapy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: children with no systemic disease;

mandibular second primary molar tooth with periradicular radiolucency Exclusion criteria: children with systemic and immunosuppressed diseases and sensitive to antibiotic drugs; hyperemic pulp

#### Age

From **4 years** old to **8 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **50**

#### 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

ethical comunity of Mashhad University of Medical Sciences

##### Street address

Vice chancellor for research , Ghoreshi building, Daneshgah street

##### City

Mashhad

##### Postal code

##### Approval date

2016-04-13, 1395/01/25

##### Ethics committee reference number

IR.mums.sd.REC.1394.95

## Health conditions studied

### 1

#### Description of health condition studied

pulpectomy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

clinical success

#### Timepoint

2 and 6 and 12 months after intervention

#### Method of measurement

examination and observation, expression by pateint

### 2

#### Description

radiographic success

#### Timepoint

2 and 6 and 12 months after intervention

#### Method of measurement

radiographic feature

## Secondary outcomes

### 1

#### Description

pain

#### Timepoint

2 and 6 and 12 months after intervention

#### Method of measurement

expression by patient

### 2

#### Description

fistula

#### Timepoint

2 and 6 and 12 months after intervention

#### Method of measurement

examination and observation

### 3

#### Description

abscess

#### Timepoint

2 and 6 and 12 months after intervention

#### Method of measurement

examination and observation

### 4

#### Description

tenderness to percussion

#### Timepoint

2 and 6 and 12 months after intervention

#### Method of measurement

examination and observation

### 5

#### Description

new radiolucent lesion

#### Timepoint

2 and 6 and 12 months after intervention

#### Method of measurement

radiographic feature

## 6

### **Description**

change in primary lesion

### **Timepoint**

2 and 6 and 12 months after intervention

### **Method of measurement**

radiographic feature

## 7

### **Description**

internal or external resorption

### **Timepoint**

2 and 6 and 12 months after intervention

### **Method of measurement**

radiographic feature

## **Intervention groups**

### 1

#### **Description**

Intervention: pulp therapy with 3 Mix Antibiotic paste, Ciprofloxacin, Metronidazole and Minocycline, volume ratio 1:3:3 respectively, once utilization

#### **Category**

Treatment - Other

### 2

#### **Description**

Control: standard pulpectomy

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Mashhad dental school

##### **Full name of responsible person**

Noorollahian Homa. Associate Professor of Pediatric Dentistry, Oral & Maxillofacial Diseases Researc

##### **Street address**

department of pedodontics,Mashhad dental school,Vakil Abad Boulevared

##### **City**

Mashhad

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research of Mashhad university of medical sciences

#### **Full name of responsible person**

Homa Noorollahian

#### **Street address**

Mashhad dental school, Vakil Abad Boulevard

#### **City**

Mashhad

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Vice chancellor for research of Mashhad 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*

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Mashhad dental school

##### **Full name of responsible person**

Homa Noorollahian

##### **Position**

Pedodontist,Associate Professor of Pediatric Dentistry

##### **Other areas of specialty/work**

##### **Street address**

Vakil Abad Boulvared

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##### **Postal code**

##### **Phone**

+98 51 3882 9501

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##### **Email**

noorollahianh@mums.ac.ir

##### **Web page address**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

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##### **Full name of responsible person**

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##### **Position**

Pedodontist

##### **Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad Dental School  
**Full name of responsible person**  
Homa Noorollahian  
**Position**  
Pedodontist, Associate Professor of Pediatric Dentistry  
**Other areas of specialty/work**  
**Street address**  
Vakil Abad  
**City**  
Mashhad  
**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*