

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

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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

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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

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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

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

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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