

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Antimicrobial Effect of intracanal medicaments (Triple Antibiotic Paste and Calcium hydroxide) Against E. Faecalis Bacteria in infected primary molars by Real-Time PCR :A Randomized Clinical Trial

Protocol summary

Study aim

The aim is to evaluate the antimicrobial efficacy of intracanal medicaments including triple paste antibiotic and calcium hydroxide against bacteria in infected primary molars

Design

A randomized clinical trial with control group, parallel groups, double blind

Settings and conduct

The aim of this study is to compare antimicrobial efficacy of calcium hydroxide and triple antibiotic paste as intracanal medicament. Therefore, 39 children 4-6 years old (pediatric department of Shiraz dental school, Shiraz university of medical sciences) will be randomly divided into three groups. First microbiological samples (S1) will be collected from the root canal then one of the aforementioned medicaments will be placed into the root canal according to the groups of the study (except the control group). Seven days later, canals will be irrigated and second bacteriological samples (S2) will be collected. The samples will be incubated and DNA extraction will be performed to count bacteria using real-time PCR. Patients and analyzers are blinded about the intracanal medicament.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children, aged 4-6 years old with infected primary molars and radiolucent periapical lesions
Exclusion criteria: Children should not receive any antibiotic at least one month before the treatment session

Intervention groups

Test group 1: Triple antibiotic paste that is inserted into the infected root canal between treatment sessions
Test group 2: Calcium hydroxide that is inserted into the infected root canal between treatment sessions
Control group 3: using just a piece of cotton pellet in pulp chamber without intracanal medicament

Main outcome variables

1. Changes in Bacteria count in the root canals of infected teeth
2. Success rate of treatment after applying each intracanal medicament

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181226042132N1**

Registration date: **2019-05-05, 1398/02/15**

Registration timing: **retrospective**

Last update: **2019-05-05, 1398/02/15**

Update count: **0**

Registration date

2019-05-05, 1398/02/15

Registrant information

Name

Najmeh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3843 6561

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mohammadyn@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Antimicrobial Effect of intracanal medicaments(Triple Antibiotic Paste and Calcium hydroxide) Against E.Faecalis Bacteria in infected primary molars by Real-Time PCR :A Randomized Clinical Trial

Public title

Evaluation of the effect of intracanal medicaments against root canal bacteria of infected primary molar tooth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with infected primary molars tooth with periapical radiolucent lesion

Exclusion criteria:

Children should not receive any antibiotic since 1 month before the treatment session.

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

The children will be randomly divided into three groups (according to block randomization) depending on type of intracanal medicament. Blocks will be then randomly chosen to determine the patients' assignment into the groups. The group allocation will be revealed by an assistant not directly involved in the study only after each patient is seated for the initial appointment and a random code number will be assigned to each patient at the beginning of study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and the data evaluators are blinded with respect to the type of intracanal medicament used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz school of dentistry, Mehr Blvd, Ghasredasht

City

Shiraz

Province

Fars

Postal code

7195615878

Approval date

2018-12-25, 1397/10/04

Ethics committee reference number

IR.SUMS.REC.1397.828

Health conditions studied

1

Description of health condition studied

Infection of primary molars

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

Primary outcomes

1

Description

Changes in Bacteria count in the root canals of infected teeth

Timepoint

Bacteria count at the beginning and 7 days after each two type of intervention

Method of measurement

Polymerase Chain Reaction

2

Description

Success rate of treatment after applying each intracanal medicament

Timepoint

recording the clinical status(pain,mobility,swelling,..)and radiography(extension of the radiolucent lesion,bone resorption,..)at the beginning before the intervention and then two months after the treatment.

Method of measurement

examination and record of pain history,mobility grade(1,2,3), examination of swelling status,bone density

measurement from radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1:triple antibiotic paste containig minocycline ,ciprofloxacin and metronidazole,once between sessions for 7 days in the root canal system

Category

Treatment - Drugs

2

Description

Intervention group 2: Calcium Hydroxide,once between sessions for 7 days in the root canal system

Category

Treatment - Drugs

3

Description

Control group: No medicament; rinsing with normal saline and using a piece of cotton pellet in pulp chamber between treatment sessions

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz school of dentistry

Full name of responsible person

Dordaneh Ghaffaripour

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Shiraz school of dentistry, Mehr Blvd, Ghasredasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Faghihi

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dordaneh Ghaffaripour

Position

Resident of pediatric dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

Najmeh Mohammady

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available