Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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,39children 4-6 years old (pediatric department of shiraz dental school,shiraz university of medical sciences)will be randomly divided into thee 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 recieve any antibiotic at least one month before the treatment session

Intervention groups

Test group1 :Triple antibiotic paste that is inserted into the infected root canal between treatment sessions Test group2 :Calcium hydroxide that is inserted into the infected root canal between treatment sessions Control group3 : 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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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 recieve 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 radigraphy(extension of the radiolucent lesion,bone resorption,...)at the begining 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
Ḍordaneh Ghaffaripour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Medical doctor
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Person responsible for scientific inquiries

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Shiraz University of Medical Sciences

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Position
Assistant professor

Latest degree
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Person responsible for updating data

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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