

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of using children's protaper rotary file and manual file in reducing the amount of Enterococcus faecalis bacteria and pain in the treatment of necrotic deciduous molar

Protocol summary

Study aim

Comparison of the effect of using children's protaper rotary file and manual file in reducing the amount of Enterococcus faecalis bacteria and pain in the treatment of necrotic deciduous molar

Design

This is a randomized, non-blinded clinical trial with a parallel design. This randomized study will be conducted on 36 children with necrotic Molleridum deciduous teeth in the lower jaw. A simple randomization method is used for randomization and the participants are assigned to two intervention groups.

Settings and conduct

This study, which will be conducted in a dental office in Isfahan city, is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Milk molar tooth with necrotic pulp; Necrotic second molar teeth Exclusion criteria: External and internal analysis of teeth; A clear lesion of the furca of the second molar

Intervention groups

In the first intervention group, the canals are prepared using children's Protiper rotary files. Children's rotary files are filed with numbers 20, 25, and 30. After complete filing, a sample is taken from the distal canal again using a paper cane number 40 and transferred to the normal saline environment. Ten dilutions are prepared from each sample and 100 microliters of each dilution is cultured in the blood agar medium. In the second intervention group, we used manual files to clean the channels. In this way, first using the manual file number 15 and after determining the length of the channels from the graph, the cleaning of the channels starts with the filing movement. Then it ends with files number 20, 25, and 30, respectively, of cleaning the channels.

Main outcome variables

The Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N208**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **prospective**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

Registration date

2023-08-26, 1402/06/04

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of using children's protaper rotary file and manual file in reducing the amount of Enterococcus faecalis bacteria and pain in the treatment of necrotic deciduous molar

Public title
Comparison of the effect of using two methods of preparation in reducing the amount of bacteria and pain in the treatment of milk teeth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Informed consent Milk molar tooth with necrotic pulp
 Necrotic second molar teeth Age between 5 - 10 years
Exclusion criteria:
 External and internal analysis of teeth .. A clear lesion of the furca of the second molar

Age
From **5 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done in a simple random method, after identifying eligible patients, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned in the first intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the second intervention group

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Islamic Azad University, Khorasgan branch

Street address
Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street

City
Isfahan

Province
Isfahan

Postal code
8155139998

Approval date
2023-08-15, 1402/05/24

Ethics committee reference number
IR.IAU.KHUISF.REC.1402.169

Health conditions studied

1

Description of health condition studied

Necrotized primery molars

ICD-10 code

K02.5

ICD-10 code description

Caries with pulp exposure

Primary outcomes

1

Description

The pain

Timepoint

The beginning of the study and the end of the study

Method of measurement

Based on visual pain scale

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, the canals are prepared using children's Protiper rotary files. Children's rotary files are filed with numbers 20, 25 and 30. After complete filing, a sample is taken from the distal canal again using a paper cane number 40 and transferred to the normal saline environment. Ten dilutions are prepared from each sample and 100 microliters of each dilution is cultured in the blood agar medium.

Category

Treatment - Other

2

Description

In the second intervention group, we use manual files to

clean the channels. In this way, first using the manual file number 15 and after determining the length of the channels from the graph, the cleaning of the channels starts with the filing movement. Then it ends with files number 20, 25 and 30, respectively, of cleaning the channels.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Sadouq Clinic

Full name of responsible person

Shadi Shirmardi

Street address

41 Alley, Between Sheikh Mofid Three Roads and Nikbakht Crossroads,

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Islamic Azad University of Isfahan, Khorasgan branch

Full name of responsible person

Dr. Majid Meshkini

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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

Islamic Azad University of Isfahan, Khorasgan branch

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**

Islamic Azad University of Isfahan, Khorasgan branch

Full name of responsible person

Shadi Shirmardi

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Parisa Ranjbarian

Position

University faculty member

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

A Level or less

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 further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available