

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### 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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meshkini@miums.ac.ir

**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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Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University of Isfahan, Khorasgan branch

**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**

**Contact**

**Name of organization / entity**

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**Position**

Dental student

**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