

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy evaluation of manual and Race rotary files in root canal preparation of primary molars: an in vivo study

Protocol summary

Study aim

Efficacy determination and comparison of manual and Race rotary files in root canal preparation of primary molars

Design

A randomized, double blinded, controlled clinical trial with a parallel group design of 20 patients.

Settings and conduct

Based on the population of 5 up to 9 years old children, needy to pulpectomy of infectious necrotic primary molars, in the pediatric dentistry department of Qazvin dental school, by the blindness of children, evaluators, and analyzer.

Participants/Inclusion and exclusion criteria

Children 5 up to 9 years old, needy to pulpectomy of infectious necrotic primary molar

Intervention groups

Based on age, Patients will divide into two strata. Each stratum will be grouped into pulpectomy by manual instrument or Race rotary file. Eventually, according to the preparation period, microbial evaluation and child cooperation, the efficacy of rotary and the manual instrument will be compared.

Main outcome variables

Duration of intervention by each of instrument;
Cooperation scale of the child throughout intervention;
The microbial load of the canal before and after chemomechanical preparation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180429039468N1**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **prospective**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-06, 1397/07/14

Expected recruitment end date

2018-11-05, 1397/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy evaluation of manual and Race rotary files in root canal preparation of primary molars: an in vivo study

Public title

Efficacy of Race rotary files in root canal preparation of primary molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

healthy child none of a history of the chronic systemic disease the cooperation basis on frankle criteria (3 and 4 groups) the restorable tooth with the suitable structure for rubber dam caries with the history of spontaneous and night pain at least two-thirds of the root present normal morphology moderate root angulation (root curvature radius 10-20m, the angle of the curvature 25-39 degrees) radiographic signs of pulp complication, consist of thin trabeculae, radiolucency of furcation and PDL widening acute alveolar abscess and fistulae

Exclusion criteria:

physical or mental disability of the child antibiotic receipt in two last weeks former pulp therapy inadequate root length obstructed and calcified canal fractured root pathological internal or external root resorption internal or external furcation perforation severe bone resorption, affecting the permanent tooth crypt type II canals presence of two distally canals in mandibular molars

Age

From **5 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will select upon nonrandomization simple sampling (convenience sample), between those referred for primary molars pulpectomy to the pediatric dentistry department of Qazvin dental university. With Win Pepi software they will be randomly allocated into two stratifies, 5< up to 7 years and 7< up to 9 years.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the description of intervention methods to parents/guardians, the kind of instrument will specify for the operator, upon software allocation. The operator won't be blind, due to the different types of instrument. Via lack of awareness of the investigation's aims, the child and the collector of time will be considered blind. The evaluator and collector of microbiologic data will be blind, through coded samples. By overlaying the monitor, the evaluator and collector of cooperation data will be blind. The analyzer will be blind, on coded patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qazvin University of Medical Sciences

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Shahid Bahonar Blvd

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Approval date

2017-08-18, 1396/05/27

Ethics committee reference number

IR.QUMS.REC.1396.224

Health conditions studied**1****Description of health condition studied**

infectious necrotic primary molars

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

Primary outcomes**1****Description**

Change of the microbial load of canal following instrumentation by manual or rotary file

Timepoint

Sampling before and after chemomechanical preparation of canal at the same session

Method of measurement

Count of colony forming units after aerobic and anaerobic bacterial culture

2**Description**

Instrumentation time throughout the manual or rotary file

Timepoint

At the period of canal preparation by the manual or rotary file

Method of measurement

Chronometer

3

Description

Cooperation scale of the child throughout instrumentation

Timepoint

At the period of canal preparation by the manual or rotary file

Method of measurement

Ohio state university behavioral rating scale(OSUBRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Canal preparation through Race rotary file 2% tapered

Category

Treatment - Devices

2

Description

Control group: Canal preparation through manual instrument 2% tapered

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Department of Dental school of Qazvin University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

Undecided - It is not yet known if there will be 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