Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of two rotary file systems with manual instrumentation for root canal preparation in primary teeth: a randomized clinical trial

Protocol summary

Study aim
clinical comparison of two rotary file systems with manual instrumentation in root canal preparation of primary molars Objectives: 1. Determination of the time of canal preparation for two rotary file systems (FKG iRace plus and M3-immatural) and hand file (K-file) 2. Determination of the time of obturation for two rotary file systems (FKG iRace plus and M3-immatural) and hand file (K-file) 3. Determination of patient cooperation during the canal preparation with rotary file systems (FKG iRace plus and M3-immatural) and hand file (K-file) 4. Determination of intensity and duration of pain immediately after the treatment and during the 6, 12, 24, 48, and 72 hours and 1 week after treatment 5, 6. Determination of clinicaland radiographic success rate for two rotary file systems (FKG iRace plus and M3-immatural) and hand file (K-file) during the 6, 12 and 18 months after treatment.

Design
Randomised, parallel group trial, double-blinded, randomised with randomisation application

Settings and conduct
Pediatric Dentistry Department

Participants/Inclusion and exclusion criteria
children with systemic diseases or with special healthcare needs Children with poor oral hygiene or periodontal disease radiographic signs of internal or external root resorption, root canal calcification, non-restorabale teeth

Intervention groups
group 1: root canal preparation with hand files (Control group) group 2: root canal preparation with rotary file system (M3-immatural, G. T. A., China) group 3: root canal preparation with rotary file system (FKG, iRace Plus)

Main outcome variables
time of canal preparation and obturation, patient cooperation, pain duration and intensity, clinical and radiographic success

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110823007402N8**
Registration date: **2022-03-04, 1400/12/13**
Registration timing: **prospective**

Last update: **2022-03-04, 1400/12/13**
Update count: **0**

Registration date
2022-03-04, 1400/12/13

Registrant information

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Shiraz University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-03, 1401/01/14

Expected recruitment end date
2022-06-21, 1401/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of two rotary file systems with manual instrumentation for root canal preparation in primary teeth: a randomized clinical trial

Public title
Rotary file system in primary teeth

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
clinical examination reveals carious lesion in primary molar without extension to the root vital signs during the intervention will be checked and only vital teeth are included in the study All cases report signs of irreversible pulpitis with chief complaint of spontaneous pain in the past few days. This pain is exacerbated with clod or warm stimuli and the patient requires analgesic consumption. minimum of two thirds of root remainings Children of 5-8 years old

Exclusion criteria:
children with systemic diseases or with special healthcare needs Children with poor oral hygiene or periodontal disease radiographic signs of internal or external root resorption, root canal calcification, non-restorabale teeth

Age
From **5 years** old to **8 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patient selection is based on the block randomization method with the use of randomization application. For the concealment, Sequentially numbered, sealed, opaque envelopes are used.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient and the two researches who record the time of canal preparation and obturation, pain intensity, and child cooperation during the intervention and also the researcher who interprets the quality of obturation, clinical and radiographic success are blind to the group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz Dental School

Street address
Shiraz Dental School, Qom Abad street, Qasrodasht avenue

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7196515878

Approval date
2022-01-05, 1400/10/15

Ethics committee reference number
IR.SUMS.DENTAL.REC.1400.130

Health conditions studied

1

Description of health condition studied
Primary second molar with irreversible pulpitis

ICD-10 code
K04.0

ICD-10 code description
Pulpitis

Primary outcomes

1

Description
measurement of time of canal preparation with chronometer

Timepoint
From initiation to the end of filing

Method of measurement
with chronometer

2

Description
measurement of time of canal obturation with chronometer

Timepoint
From initiation to the end of obturation

Method of measurement
with chronometer

3

Description
patient cooperation

Timepoint
during intervention
Method of measurement
Frankel and FLACC criteria for patient cooperation

4

Description
Intensity and duration of pain
Timepoint
6, 12, 24, 48, 72 hours and 1 week after intervention
Method of measurement
four point pain intensity

5

Description
clinical success
Timepoint
3, 6, 12, and 18 months after treatment
Method of measurement
without signs of pain, abscess, redness, tenderness, mobility, swelling, sinus tract, and pus are considered successful

6

Description
radiographic success
Timepoint
3, 6, 12, and 18 months after treatment
Method of measurement
absence of pathologic findings, radiolucency in furca or periapical

Secondary outcomes

empty

Intervention groups

1

Description
Control group: After access cavity preparation, the root canal will be prepared with hand file. Sodium hypochlorite and normal saline and EDTA (if needed) is used for canal irrigation and lubrication. Each file will be used for 4 teeth maximum. The prepared canals are then dried with paper cones (size 30-35) and filled with Endoflas (Sanlor and Cia. S. en C.S., Cali, Colombia) 1-2 mm shorter than the working length using injection method with Navitip (Ultradent, USA)
Category
Treatment - Devices

2

Description
Intervention group: After access cavity preparation, the root canal will be prepared with rotary file m3-immatural. Sodium hypochlorite and normal saline and EDTA (if needed) is used for canal irrigation and lubrication. Each file will be used for 4 teeth maximum. The prepared canals are then dried with paper cones (size 30-35) and filled with Endoflas (Sanlor and Cia. S. en C.S., Cali, Colombia) 1-2 mm shorter than the working length using injection method with Navitip (Ultradent, USA)
Category
Treatment - Devices

3

Description
Intervention group: After access cavity preparation, the root canal will be prepared with Rotary file iRace plus. Sodium hypochlorite and normal saline and EDTA (if needed) is used for canal irrigation and lubrication. Each file will be used for 4 teeth maximum. The prepared canals are then dried with paper cones (size 30-35) and filled with Endoflas (Sanlor and Cia. S. en C.S., Cali, Colombia) 1-2 mm shorter than the working length using injection method with Navitip (Ultradent, USA)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Pediatric Dentistry, Shiraz Dental School
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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

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

Mahtab Memarpour

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Latest degree

Specialist

Other areas of specialty/work

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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