

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of obturation quality and root canal treatment time between Neolix and M3 Immatural rotary systems and hand instrument in primary mandibular molars: a single blind randomized clinical trial

Protocol summary

Study aim

Comparison of obturation quality and root canal treatment time between Neolix and M3 Immatural rotary systems and hand instrument in primary mandibular molars: a single blind randomized clinical trial

Design

Clinical trials with a control group, with parallel groups, single-blinded, randomized. Children will be divided into three groups in a simple random way (using Excel software).

Settings and conduct

The study will be conducted on patients referring to the Pediatric Department of Babol Dental School, who will be required pulpectomy in any of the deciduous mandibular molars. Sampling was done randomly and for each treatment group, 10 samples and a total of 30 samples will be considered. The assessment of obturation quality will be done by an endodontist who is blind to the type of instrumentation (single-blinded).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 4 to 9 years, vital or necrotic mandibular primary molars without sinus tract, absence of internal or external pathological root resorption, at least two-thirds of remaining root length, children exhibiting Frankl's behavior rating scale score of 3 and 4, presence of adequate coronal tooth structure to receive stainless steel (SS) crown or, amalgam restoration and signature of consent form. Exclusion criteria: children with underlying systemic diseases and those with special healthcare needs, children lacking cooperative ability, teeth with more than one-third of pathological root resorption, radiolucent area(s) in the radiography and teeth that cannot be restored.

Intervention groups

The first group (Hand K-files), the second group (M3 Immatural rotary file) and the third group (Neoniti A1 rotary files).

Main outcome variables

The investigated parameters include: obturation quality and treatment time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056551N1**

Registration date: **2023-02-13, 1401/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-13, 1401/11/24**

Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Mostafa Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9592

Email address

mo.abbasi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of obturation quality and root canal treatment time between Neolix and M3 Immatural rotary systems and hand instrument in primary mandibular molars: a single blind randomized clinical trial

Public title

Comparison of obturation quality and root canal treatment time between Neolix and M3 Immatural rotary systems and hand instrument in primary mandibular molars

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 4 to 9 years. Vital or necrotic mandibular primary molars without sinus tract. Absence of internal or external pathological root resorption. At least two-thirds of remaining root length. Children exhibiting Frankl's behavior rating scale score of 3 and 4. Presence of adequate coronal tooth structure to receive Stainless Steel (SS) crown or amalgam restoration. Signature of consent form.

Exclusion criteria:

Children with underlying systemic diseases and those with special healthcare needs. Children lacking cooperative ability. Teeth with more than one-third of pathological root resorption. Radiolucent area(s) in the radiography. Teeth that cannot be restored.

Age

From **4 years** old to **9 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Children are selected by the available and improbable method, and among them, children who meet the eligible criteria will be selected. Then 30 children will be divided into three groups by random allocation method and using random numbers obtained from Excel software, and 10 people will be treated in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessment of obturation quality will be done by an endodontist who will be blinded to the type of instrumentation.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol univercity of medical science

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2022-10-30, 1401/08/08

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.166

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

Necrosis of pulp

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

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

Obturation quality

Timepoint

Immediately after root canal obturation

Method of measurement

The obturation quality will be graded as optimal fill, overfill, and underfill (by Coll JA and Sadrian R 1996).

2**Description**

Treatment time

Timepoint

Time to prepare and obturate the root canal.

Method of measurement

by stopwatch

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Root canal instrumentation will be done using M3 Immatural (#20) rotary files.

Category

Treatment - Devices

2

Description

Control group: Root canal preparation will be done using Hand K-files from #15 to #30 employing a quarter pull turn method.

Category

Treatment - Devices

3

Description

Intervention group: Root canal instrumentation will be done using Neoniti A1 rotary files (#25).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric departmet of Babol dental faculty

Full name of responsible person

Mostafa Abasirostami

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 2291 4089

Email

mo.abbasi@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Efati Khodadai

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3220 7918

Email

drekhodadadi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mostafa Abasirostami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

0098 11 2291408

Email

mo.abbasi@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences
Full name of responsible person
Efat Khodadadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Ganjafrooz Ave.
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
0098 11 2291408
Email
drekhodadadi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mostafa Abasirostami
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry

Street address
Ganjafrooz Ave.
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
0098 11 2291408
Email
mo.abbasi@mubabol.ac.ir

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