Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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. Efat 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