Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluating the effect of NeoPUTTY as an apical plug used in mandibular first molar in postoperative pain and flare up; a randomized clinical trial

Protocol summary

Study aim
evaluating pain and flare-up after treatment following the use of NeoPUTTY as an apical plug in mandibular first molar teeth

Design
The study is conducted as a single-center double-arm trial. Thirty patients will be divided into two equal groups (15 patients each).

Settings and conduct
Department of Endodontics, Faculty of Dentistry, Mashhad

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Patients in the age range of 6 to 15 years • Necrotic immature mandibular first molar with open apex (size 60 to 100) • A tooth with chronic apical periodontitis with a radiolucency greater than 3 mm2 in periapical radiography. • A tooth without tract sinus, no drainage from the canal, no swelling and no acute apical periodontitis • Patients should not have pain in the desired tooth area before starting the treatment • Patients have not received any medicine before starting the treatment Non-entry criteria: • Teeth with root fractures, resorption or calcifications • Non-cooperative child • Teeth with damaged periodontal structure, severe mobility

Intervention groups
Shaping and cleaning of the tooth root canal is done using Protaper rotary file system up to number F3. Irrigation 2.5% sodium hypochlorite using a 27-gauge side vent needle and activation with the sonic Endoactivator device. In the first group, OrthoMTA and in the second group, NEOPUTTY will be prepared, it will be taken into the canal using System MAP One and will be condensed into a 3-5 mm thick plug at the apical end of the root canal. Then, in both groups, the canal will be temporarily restored using cavit, and the second session 24 hours later, canal obturation will be performed using warm vertical compression technique with AH 26 sealer. Three, 6, 12, 24, 48 and 72 hours after root canal treatment, the patient's pain and swelling are evaluated according to VAS criteria.

Main outcome variables
Pain; swelling; flare-up

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240607062028N1**
Registration date: **2024-08-28, 1403/06/07**
Registration timing: **prospective**

Last update: **2024-08-28, 1403/06/07**
Update count: **0**

Registration date
2024-08-28, 1403/06/07

Registrant information

Name
Maryam Khorasanchi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-05, 1403/08/15

Expected recruitment end date
2025-05-05, 1404/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of NeoPUTTY as an apical plug used in mandibular first molar in postoperative pain and flare up; a randomized clinical trial

Public title
Evaluating the effect of NeoPUTTY as an apical plug used in 6th tooth of lower jaw in postoperative pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients in the age range of 6 to 15 years Necrotic immature mandibular first molar with open apex (size 60 to 100) A tooth with chronic apical periodontitis with the presence of a radiolucency greater than 3 mm2 in periapical radiography Tooth without sinus tract, no drainage from the canal, no swelling and no acute apical periodontitis Patients should not have pain in the area of the target tooth before starting the root canal treatment Patients should have not received any medical treatment before starting the root canal treatment Teeth without root deviation, root resorption or calcification Tooth without previous root canal treatment or crown Teeth without any root fracture or craze lines
Exclusion criteria:
Necrotic immature mandibular first molar with open apex (larger than size 100) Teeth with root fracture, craze lines, root deviation, resorption or calcifications lack of child cooperation Teeth with compromised periodontal structure, severe mobility Teeth with previous root canal treatment, post or crown Teeth with open apex and severe destruction that are unrestorable Patient unwillingness to participate Major systemic disease (ASA 3 or higher) The patient's severe pain that led to the use of analgesic
Age
From **6 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are entered into the study according to the inclusion criteria and are randomly assigned to one of the two study groups using double blocks and tap/line (coin toss). In order to ensure an equal number of intervention and control group samples in each of the mesial and distal root subgroups, first, the sample in odd sequences is assigned to the intervention or control group in the form of tap/line, and in even sequences as The reverse is done with the odd sequence of allocation. If there is a need to put a plug in both roots of the first molar of the mandible, first one of the roots is selected as a tap/line and the other root will be in the same group as the first root.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants, the evaluators for the follow-up of the patient's pain, and the statistical data analysts will not know about the study groups. Only the operator who performs the treatment process of the patients will be aware of the participants' grouping after the allocation and immediately before the treatment. As for the patients blinding, the preparation of the substance will be done away from the patient's sight.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Dentistry - Mashhad University of Medical Sciences (Ethics Committee)
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Azadi square
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Approval date
2024-03-09, 1402/12/19
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1403.019

Health conditions studied

1

Description of health condition studied
Flare-up and pain
ICD-10 code
K04.5
ICD-10 code description
Chronic apical periodontitis

Primary outcomes

1

Description
Flare-up and pain
Timepoint
3, 6, 12, 24, 48 and 72 hours postoperative
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: NeoPUTTY (Avalon Biomed Inc., Bradenton, USA). A bioceramic, bioactive MTA is premixed in a syringe. This material is placed at the apical end of the roots as a plug by MAP One (Produits Dentaires S. A., Vevey, Switzerland). Using a suitable plugger, it will be compacted in the form of a plug to reach a thickness of 3-5 mm at the apical end of the root canal. After the MTA has solidified, the excess MTA on the canal wall is gently wiped off with wet cotton. According to the manufacturer's brochure, the setting time of this material is 4 hours. Therefore, a wet paper point will be placed on it and the canal is temporarily dressed with Cavit (3M ESPE, Seefeld, Germany). At the end of this session, a periapical radiograph is prepared to ensure the thickness of the placed plug. The next session, after 24 hours, if there is no pain and symptoms, under local anesthesia and rubber dam isolation, temporary dressing and wet cotton balls are removed. . The MTA setting is slowly checked with a #40k file. Obturation of the canal will be done by the hot vertical compression technique with AH 26 sealer, and the patient's root canal treatment will be completed. In total, 2 treatment sessions will take about 90 minutes each.
Category
Treatment - Other

2

Description
Control group: OrthoMTA (BioMTA, Seoul, Korea). An MTA is a powder that needs to be mixed with normal saline to achieve a sandy/creamy consistency. This material is placed at the apical end of the roots as a plug by MAP One (Produits Dentaires S. A., Vevey, Switzerland). Using a suitable plugger, it will be compacted in the form of a plug to reach a thickness of 3-5 mm at the apical end of the root canal. After the MTA has solidified, the excess MTA on the canal wall is gently wiped off with wet paper point. According to the manufacturer's brochure, the setting time of this material is 3 hours. Therefore, a wet paper point will be placed on it and the canal is temporarily dressed with Cavit (3M ESPE, Seefeld, Germany). A periapical radiograph is prepared at the end of this session to ensure the thickness of the plug. In the next session, after 24 hours, if there is no pain and symptoms, under local anesthesia and isolation of Ruberdem, the temporary dressing and wet cotton balls are removed. The MTA setting is slowly checked with a #40k file. Obturation of the canal will be done by the hot vertical compression technique with AH 26 sealer, and the patient's root canal treatment will be completed. In total, 2 treatment sessions will take about 90 minutes each
Category
Treatment - Other

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Khorasanchi

Position
Endodontics Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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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
No more info is available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Only part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long
The access period starts after the results are printed

To whom data/document is available
Researchers working in academic and scientific

institutions and people who are also engaged in industry

Under which criteria data/document could be used

Just for study and not for analysis

From where data/document is obtainable

Maryam Khorasanchi Khorasanchim4011@mums.ac.ir

What processes are involved for a request to access data/document

After receiving the request email, it will take about 2 to 4 weeks

Comments