

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 cavitec, 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

Country

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)

Street address

Azadi square

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Mashhad

Province

Razavi Khorasan

Postal code

9117941909

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

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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Maryam Khorasanchi
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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