Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Endoactivator on Postoperative Pain in necrotic teeth with Apical Periodontities, a Clinical Trial Study

Protocol summary

Study aim

The effect of endoactivator on pain after treatment of necrotic teeth with chronic apical periodontitis

Design

The clinical trial is parallel, single-blind, with a placebo, randomized, on 44 patients. Randomization will be done using a table of random numbers, and allocation concealment with the sealed envelope method.

Settings and conduct

This is a clinical trial study on 44 patients with necrotic teeth with chronic apical periodontitis score 2 or 3, which is diagnosed by radiography and negative cold test, single root and single canal, who refer to Azad Faculty of Dentistry in Tehran for routine endodontic treatment. will be done Washing is done in both groups using 40 ml of 5.0% NaOCl. Standard washing is done using a 5 cc 30 gauge syringe and a side hole made of stainless steel. For the induction group, the tip of the device continuously injects 5.0% NaOCl into the channel entrance for one minute. To check the pain after the treatment, we ask the patients to evaluate the intensity of the pain after the operation on the VAS scale at 8, 24, 48, and 72 hours after the visit.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 65 years, a necrotic tooth with chronic apical periodontitis score 2 or 3. Exclusion criteria: pregnant or lactating patients, patients who are allergic to non-steroidal anti-inflammatory drugs.

Intervention groups

For the control group, standard washing is done using a 5 cc 30 gauge syringe and a side hole made of stainless steel. For the induction group, the tip of the device continuously injects 0.5% NaOCl into the canal entrance for one minute.

Main outcome variables

Occurrence of Postoperative Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230707058704N1**
Registration date: **2023-07-25, 1402/05/03**
Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**
Update count: **0**

Registration date

2023-07-25, 1402/05/03

Registrant information

Name

Matine Mahmudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 8929

Email address

mahmudimatin1377@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Endoactivator on Postoperative Pain in necrotic teeth with Apical Periodontities, a Clinical Trial Study

Public title
The Effect of Endoactivator on Postoperative Pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
A tooth with a mature apex and no root decay Teeth without cracks and fractures Teeth without internal or external analysis Calcification and previous root treatment
Exclusion criteria:
Pregnant or lactating patients Patients who use painkillers or any anti-inflammatory drugs Patients who are allergic to non-steroidal anti-inflammatory drugs The tooth cannot be isolated
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the simple randomization method of the random number table type. Since the total number of study subjects is 44 people and a two-digit number, we give each person a two-digit code. Then, to select sample people from the table, by closing the eyes and putting the tip of the pen on the table, starting from a point of the table in the direction of the row or column, and taking into account that the code of each person is two digits, we start choosing two-digit numbers. The selected number is actually the code of an individual from the community that is selected as a sample. This continues until the number of people in the inducer group sample (22 people) can be chosen smaller than 44..In order to conceal, we use concealment allocation, which is the method used to perform a random sequence on the study participants, in such a way that the assigned group is not known before the allocation of the individual. Using opaque envelopes sealed with a random sequence (envelopes opaque, sealed, numbered sequentially), in this method, each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order They are placed.In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
After obtaining the consent form and general introduction of the study groups to the participants, the information that can cause the test result to deviate remains hidden from the participant's view, but the person responsible for conducting the test is aware of them and the study is conducted in a single blind manner.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No.166, 7th bustan, Pasdaran, Tehran
City
Tehran
Province
Tehran
Postal code
1666613966
Approval date
2023-06-14, 1402/03/24
Ethics committee reference number
IR.IAU.DENTAL.REC.1402.028

Health conditions studied

1

Description of health condition studied
necrotic teeth with apical periodontitis
ICD-10 code
K04.5
ICD-10 code description
Chronic apical periodontitis

Primary outcomes

1

Description
Pain score after root canal treatment in Visual Analogue Scale
Timepoint
Measurement of pain intensity 12 hours before treatment

and 8, 24, 48 and 72 hours after root canal treatment.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: washing the canal with an induction activator, so that the tip of the device continuously injects 0.5% sodium hypochlorite into the entrance of the canal for one minute, and each washing cycle includes placing the tip during operation for 6 seconds and then placing it in It is two millimeters shorter than the working length for another 6 seconds and repeat this again for 30 seconds.

Category

Treatment - Devices

2

Description

Control group: standard washing is done using a 5cc 30 gauge syringe with a side hole made of stainless steel, the needle goes to 3 mm working length and washing is done with 0.5% sodium hypochlorite and 17% EDTA for one minute.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry-Islamic Azad University of Medical Sciences, Tehran

Full name of responsible person

Matine Mahmudi

Street address

No. 9, Pasdaran St., Neyestan 9th

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Sohrab Tor Sawad Kohi

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Email

s_savadkoohi@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

This study is carried out independently by the student, and Tehran Azad Dental School provides the necessary background for conducting the study and field facilities and is a financial supporter.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Matine Mahmudi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

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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