Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The evaluation of different irrigation methods on postoperative pain in nonvital mandibular molars

Protocol summary

Study aim
Comparison of the use of different irrigation methods on postoperative pain in nonvital mandibular molars

Design
Randomized clinical trial with a control group, with parallel groups, single-blind, phase 2 on 80 patients.

Settings and conduct
Among the patients referred to the private practice in Sanandaj , patients who have a non-vital mandibular molar tooth in need of root canal treatment are selected. After the endodontic treatment for each patient, a final irrigation method is randomly selected from the 4 investigated methods including ultrasonic device, endoactivator, activation with gutta percha and conventional syringe and is performed for the patient. After the end of the treatment, a pain registration form for the intervals of 8, 24, 48 hours after the treatment is delivered to the patient to record her/his pain level. The patient and the person analyzing the data do not know about the final irrigation method used.

Participants/Inclusion and exclusion criteria
The inclusion criteria: patients who are willing to participate in the study and candidates for receiving root canal treatment for non-vital mandibular molar teeth. Exclusion criteria: children, people with any systemic disease and allergy to any solution and medicine and tooth with complex anatomy that require treatment in more than one session.

Intervention groups
For each individual one of the 4 irrigation methods is used including: ultrasonic, endoactivator, activation with gutta percha and conventional syringe. The control group is the group for which conventional syringes were used.

Main outcome variables
Extrusion of irrigant solution beyond the apex of the root

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240615062144N1**
Registration date: **2024-07-12, 1403/04/22**
Registration timing: **prospective**

Last update: **2024-07-12, 1403/04/22**
Update count: **0**

Registration date
2024-07-12, 1403/04/22

Registrant information

Name
Erfan Ahmadyani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 87 3324 4049

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-22, 1403/05/01

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The evaluation of different irrigation methods on postoperative pain in nonvital mandibular molars

Public title
The evaluation of active irrigation on postoperative pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for endodontic treatment for nonvital mandibular molar Candidate tooth has endodontic lesion
Exclusion criteria:
Patients with any systemic condition Candidate tooth has complicated anatomy, resorption and calcified canals.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study which is in the form of randomized blocking the researcher considers every eligible patient to enter the study as a sample then the patient chooses one card from a pack of 80 cards that on each card their is one letter based on a irrigation method. The selected method is performed on the patient and finally, the pain registration form is delivered to the patient and the patient registers her pain.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patient and analyzer person do not know about technique of irrigation used for patient' tooth.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdestan University of Medical Sciences
Street address
Pasdaran Street
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Approval date
2024-06-10, 1403/03/21
Ethics committee reference number
IR.MUK.REC.1403.059

Health conditions studied

1

Description of health condition studied
Evaluation of effectiveness of activation irrigation methods compared to the conventional method in reducing pain after root canal treatment in non-vital mandibular molar teeth.
ICD-10 code
S00.5
ICD-10 code description
Superficial injury of lip and oral cavity

Primary outcomes

1

Description
Postoperative pain intensity
Timepoint
8,24 and 48 hours after treatment
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who are candidates for root canal treatment for their non-vital mandibular molar teeth and have visited the personal office of Dr. Erfan Ahmadiani between August and September 1403. These patients are randomly divided into 4 groups. For the first intervention group,5.25% sodium hypochlorite irrigant is placed inside the pulp chamber and canals as the final washing step after performing all the usual steps of root canal treatment. Then with appropriate gutta percha in size and taper for prepared canal irrigant raised and lowered in the coronoapical direction, in this way, the irrigant solution is activated in the canal for 60 seconds . After active irrigation the canals will obturated in the same conditions. The patient does not know the irrigation method used for her/his tooth. After the end of the treatment process, the patient is given a form containing a visual analog scale that the patient records the level of pain at specific time intervals.

Category
Treatment - Devices

2

Description
Intervention group: Patients who are candidates for root canal treatment for their non-vital mandibular molar teeth and have visited the personal office of Dr. Erfan Ahmadiani between August and September 1403. These patients are randomly divided into 4 groups. For the second intervention group, after performing all the usual steps of root canal treatment, as the final irrigation step, the method of activating the 5.25% sodium hypochlorite irrigant solution with the sonic inducer device from Dentsply company is used. In this group, sodium hypochlorite is placed in the pulp chamber and canals and the tip of the device is placed in the canals and the solution is activated for 60 seconds. After active irrigation the canals will obturated in the same conditions. The patient does not know the irrigation method used for her/his tooth. After the end of the treatment process, the patient is given a form containing a visual analog scale that the patient records the level of pain at specific time intervals.

Category
Treatment - Devices

3

Description
Intervention group: Patients who are candidates for root canal treatment for their non-vital mandibular molar teeth and have visited the personal office of Dr. Erfan Ahmadiani between August and September 1403. These patients are randomly divided into 4 groups. For the third intervention group, after performing all the usual steps of root canal treatment, as the final irrigation step, the activation method of 5.25% sodium hypochlorite solution with the ultrasonic inductor device from Eighteeth company is used. In this group, sodium hypochlorite is placed in the pulp chamber and channels, and then the tip of the device is placed in the channels and the irrigant solution is activated for 60 seconds. After active irrigation the canals will obturated in the same conditions. The patient does not know the irrigation method used for her/his tooth. After the end of the treatment process, the patient is given a form containing a visual analog scale that the patient records the level of pain at specific time intervals

Category
Treatment - Devices

4

Description
Control group: Patients who are candidates for root canal treatment for their non-vital mandibular molar teeth and have visited the personal office of Dr. Erfan Ahmadiani between August and September 1403. These patients are randomly divided into 4 groups. For the fourth group, which is the control group, conventional side vented syringes are used as the final irrigation method after the end of the usual procedures of root canal treatment. 5.25% sodium hypochlorite irrigant solution is passively placed in the pulp chamber and canals for 60 seconds with conventional syringes. After passive irrigation the canals will obturated in the same conditions. The patient does not know the irrigation method used for her/his tooth. After the end of the treatment process, the patient is given a form containing a visual analog scale that the patient records the level of pain at specific time intervals.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Personal office of Dr. Erfan Ahmadyani

Full name of responsible person
Erfan Ahmadyani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Afshin Maleki

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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
Sanandaj 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
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Gona Momeni
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data potentially shareable after unidentified individuals.
When the data will become available and for how long
Access starts after publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used

Researchers have access to data under any circumstances

From where data/document is obtainable

For more information, you can contact the corresponding author via the following email: ahmadyanierfan1@gmail.com

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

The applicant has unlimited access to the data after sending the request via email to the corresponding author.

Comments