Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison and effect of activation irrigation with Ultra X device , Wave Q device and conventional irrigation of root canal with endodontic needle on postoperative endodontic pain

Protocol summary

Study aim
The aim of this study was to evaluate and compare the effects of irrigant activation using the WaveQ device, the Ultra X device, and conventional syringe-and-needle irrigation on postoperative pain following root canal treatme

Design
This study was a phase III, randomized, double-blind, controlled clinical trial with parallel groups conducted on 39 patients. Eligible patients were ran/domly assigned to one of the three study groups (Groups 1, 2, 3)

Settings and conduct
Patients referred to the Endodontics Department of Islamic Azad University, Khorasgan Branch, who are candidates for root canal treatment of mandibular premolars and meet the inclusion criteria of the study, will be randomly assigned to one of the three groups (1, 2, or 3) after providing a full explanation of the study and obtaining written informed consent. Post-treatment pain intensity will be measured at 6, 12, 24, 48, and 72 hours, as well as one week after completion of treatment, using the Visual Analogue Scale (VAS).

Participants/Inclusion and exclusion criteria
In this randomized clinical trial, 39 patients with symptomatic irreversible pulpitis of mandibular premolars (Visual Analogue Scale ≥54) were enrolled. Following local anesthesia and isolation, canals were prepared to size F2 using rotary files, with 5.25% sodium hypochlorite (NaOCl) irrigation between each file. Patients were randomly assigned to three groups (n=13): Ultra X, Wave Q, and conventional needle irrigation. After single-visit obturation (gutta-percha/AH26) and temporary restoration, pain intensity was recorded via VAS at 6, 12, 24, 48, 72 hours, and 1 week. Data were analyzed using Kruskal–Wallis, Friedman, Chi-square/Fisher's exact and Mann–Whitney U tests.

Intervention groups
1. using endodontic needle 2.activation with sonic device
3. activation with ultrasonic device

Main outcome variables
endodontic post operative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260615069816N1**
Registration date: **2026-06-27, 1405/04/06**
Registration timing: **retrospective**

Last update: **2026-06-27, 1405/04/06**
Update count: **0**

Registration date
2026-06-27, 1405/04/06

Registrant information

Name
Zahra Mohammadi

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
2025-09-25, 1404/07/03

Expected recruitment end date
2026-04-15, 1405/01/26

Actual recruitment start date

2025-09-25, 1404/07/03

Actual recruitment end date

2026-04-15, 1405/01/26

Trial completion date

empty

Scientific title

Comparison and effect of activation irrigation with Ultra X device , Wave Q device and conventional irrigation of root canal with endodontic needle on postoperative endodontic pain

Public title

Comparison and effect of activation irrigation solution on postoperative endodontic pain

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patients with good systemic health and no significant medical conditions (ASA I or II).2. Patients diagnosed with irreversible pulpitis with spontaneous pain and symptomatic apical periodontitis in single-rooted, single-canal premolar teeth.3. Patients capable of understanding the Visual Analog Scale (VAS) for pain assessment.4. Patients aged between 18 and 55 years.5. Patients who are willing to participate in the study and are able to provide written informed consent.6. Patients who are candidates for single-visit endodontic treatment

Exclusion criteria:

1. Patients with systemic diseases.2. Pregnant women and breastfeeding mothers.3. Patients requiring antibiotic prophylaxis.4. Patients with psychiatric disorders.5. Patients with a history of allergy to the medications or materials used in the study.6. Patients who had taken antibiotics or analgesics within 12 hours prior to treatment.7. Patients with a current or previous history of abscess formation or swelling in the periapical region.8. Teeth presenting any of the following conditions were excluded from the study: - Open apex or a wide apical foramen. - Necrotic teeth. - Presence of a fistula or sinus tract. - Acute or chronic periapical abscess. - Teeth with Grade II or III mobility. - Non-restorable or hopeless teeth. - Abnormal root canal anatomy or calcified canals.9. Teeth in which procedural errors occurred during root canal treatment.10. Teeth in which apical patency could not be established.11. Patients who developed a flare-up following treatment.12. Patients with stress, as determined by the stress assessment test

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **39**

Actual sample size reached: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

The methodology section has been revised to provide detailed clarification regarding participant allocation. Randomization was performed using a simple lottery-based allocation method with opaque folded papers corresponding to each intervention group. Allocation was conducted prior to the irrigation procedure to minimize selection bias

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was designed as a single-blind randomized clinical trial in which the patients were unaware of the irrigation activation method used during treatment. Due to the nature of the intervention, operator blinding was not feasible

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Azad Islamic University Khorasgan branch

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Daneshgah Blvd , Arghavanie , east jey avenue , Isfahan

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Postal code

81595158

Approval date

2025-06-21, 1404/03/31

Ethics committee reference number

IR.IAU.KHUISF.REC.1404.235

Health conditions studied

1

Description of health condition studied

Post operative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
post operative pain
Timepoint
6, 12, 24, 48 , 72 hour and 1 week after treatment
Method of measurement
VAS pain score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: type of activation irrigation solution
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
dentistry school of Azad Islamic university (khorasgan branch)
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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
Islamic Azad University
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

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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
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
post operative pain
When the data will become available and for how long
1 year after publication
To whom data/document is available
dentists
Under which criteria data/document could be used
for more research
From where data/document is obtainable
researcher
What processes are involved for a request to access data/document
6 month
Comments