

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 treatment

Design

This study was a phase III, randomized, double-blind, controlled clinical trial with parallel groups conducted on 39 patients. Eligible patients were randomly 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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Isfahan
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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)

Full name of responsible person

maryam zare jahromi

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Sponsors / Funding sources

1

Sponsor

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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

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

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

maryam zare jahromi

Position

professor

Latest degree

Specialist

Other areas of specialty/work

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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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Zahra mohammadi

Position

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Latest degree

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