

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Clinical evaluation of post-operative pain in patients with single rooted teeth with apical periodontitis requiring non-surgical endodontic retreatment after three different supplementary irrigation protocol

Protocol summary

Study aim

As post operative pain in teeth requiring non surgical retreatment is a common and unpleasant situation, this study could help decreasing patient's post endodontic pain using three different supplementary irrigation protocol

Design

Randomized clinical trial, blinded, with parallel groups design of 60 patients, between September 2021 and march 2022

Settings and conduct

In this study we are evaluating post endodontic pain in 60 patients with single root teeth referring to the khurasgan dental department who met the inclusion criteria. The prevalence and intensity of post operative pain after three different activation of irrigation PUI, XP-endo Finisher files and gentle file system would be analyzed.

Participants/Inclusion and exclusion criteria

18-65 years old healthy patients who has indication of retreatment and experienced moderate-to-severe pain represented on a visual analogue scale (VAS) and status of the periapical tissues were 3 or more according to the periapical index (PAI). patients having severe pain and/or acute apical abscesses, using analgesics within the last 12 hours or any kind of anti inflammatory or narcotics, allergic to the non-steroidal anti-inflammatory drugs. and also patients with gastrointestinal disorders and pregnant or nursing women will exclude from the study

Intervention groups

According to the final irrigation activation procedures patients would divided into one of these three separate groups: Group 1: Final irrigation activation with Passive Ultrasonic Irrigation(PUI) Group 2: Final irrigation activation with Gentlefile system Group 3: Final irrigation activation with XP-endo Finisher files.

Main outcome variables

Pain intensity, Pain prevalence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051147N1**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **retrospective**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Sadaf Mahmoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3535 4001

Email address

sadaf.mahmoudi@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

2021-09-23, 1400/07/01

Actual recruitment end date

2022-06-01, 1401/03/11

Trial completion date

2022-06-01, 1401/03/11

Scientific title

Clinical evaluation of post-operative pain in patients with single rooted teeth with apical periodontitis requiring non-surgical endodontic retreatment after three different supplementary irrigation protocol

Public title

Evaluation of post-operative pain after three different supplementary irrigation protocol in non-surgical endodontic retreatment cases

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Volunteer patients ranging between 18 and 65 years in age. Completely healthy patients Patients with single rooted teeth with apical periodontitis and up to 5 degrees curve requiring non-surgical endodontic retreatment which referred to the dental department of Khurasgan university Patients that experienced moderate-to-severe pain (4-10)—represented on a visual analogue scale (VAS) Single-rooted teeth with a PAI score of 3 or more

Exclusion criteria:

Patients with severe systemic problems Patients below 18 and above 65 years old Patients who referred with severe pain or acute periapical abscess Patients were using medication such as analgesics or any kind of anti-inflammatory drugs Patients were allergic to articaine or non-steroidal anti inflammatory drugs (NSAID) Patients using narcotics Patients with gastrointestinal disorders Patients who were pregnant or lactating Patients for whom proper primary endodontic treatment was impossible The presence of other teeth requiring RCT

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization all the patients assigned to one of the 3 experimental groups using computer sourced random table (www.rando.m.org) by a person who did not include in the study. Randomization group number and patient serial number was in the dark envelope which was opened prior to the treatment by the operator to identify which patient belonged to which group

Blinding (investigator's opinion)

Single blinded

Blinding description

Randomization group number and patient serial number was in the dark envelope which was opened prior to the treatment by the operator to identify which patient belonged to which group. Patient were acknowledged about the study and the devices were used but not aware which system was used among the experiment

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Khurasgan University of Medical Sciences

Street address

No21, Sedaghat Alley, Babol Ave, Ghaemshahr Town, Mazandaran

City

Isfahan

Province

Isfahan

Postal code

4765883844

Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.IAU.KHUISF.REC.1400.276

Health conditions studied**1****Description of health condition studied**

Post endodontic pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain intensity

Timepoint

6,12,24,48,72 hours after endodontic treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: passive ultrasonic irrigation, noncutting tip of U-file ultrasonic tips, tip diameter 20 and taper 0.01%, activation for 20 seconds

Category

Treatment - Devices

2

Description

Intervention group: gentle file system finishing brushes, up and down movements, activation for 2 minutes

Category

Treatment - Devices

3

Description

Intervention group: XP-endo Finisher files, gentle 7-8 millimeter up and down movement, activation for 1 minute

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Isfahan (Khurasgan) Branch

Full name of responsible person

Sadaf Mahmoudi

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No21, Sedaghat Alley, Babol Ave, Ghaemshahr Town, Mazandaran

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mahmoudi.sadaf@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

30

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

Sadaf Mahmoudi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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