Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 2021and 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 3experimental 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
Isfehan

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
Street address
No21, Sedaghat Alley, Babol Ave, Ghaemshahr Town, Mazandaran
City
Khurasgan
Province
Isfehan
Postal code
4765883844
Phone
+98 11 4226 3883
Email
mahmoudi.sadaf@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sadaf Mahmoudi
Street address
No21, Sedaghat Alley, Babol Ave, Ghaemshahr Town, Mazandaran
City
Khurasgan
Province
Isfehan
Postal code
4765883844
Phone
+98 11 4226 3883
Email
mahmoudi.sadaf@yahoo.com
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
Street address
No21, Sedaghat Alley, Babol Ave, Ghaemshahr Town, Mazandaran
City
Khurasgan
Province
Isfehan
Postal code
4765883844
Phone
+98 11 4226 3883
Email
mahmoudi.sadaf@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Islamic Azad University

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Phone
+98 11 4226 3883

Email
mahmoudi.sadaf@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

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Position
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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