

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of intra-canal cryotherapy on postoperative pain in single-visit endodontic retreatment: randomized clinical trial

Protocol summary

Study aim

Evaluating the effect of intracanal cryotherapy with normal saline on post-operative pain in single visit root canal treatment in single-rooted anterior and premolar teeth.

Design

A two-armed randomized clinical trial with a control group, double-blind (patient and researcher responsible for data analysis), on 46 patients.

Settings and conduct

Patients in both the intervention and control groups at the Faculty of Dentistry of Tehran University of Medical Sciences undergo non-surgical root canal retreatment and after the treatment, they are given a form to record the amount of pain after the treatment and the number of painkillers consumed for a week.

Participants/Inclusion and exclusion criteria

Patients in need of non-surgical root canal retreatment in anterior teeth and single-rooted premolars who do not have pain before treatment and are in the ASA I and ASA II groups in terms of systemic health are included in the study. Patients who have taken analgesics or antibiotics before the treatment or have a history of chronic maxillofacial pain are not included in the study. In case of swelling, sinus tract, periodontal disease, and irreparable coronal destruction, patients are excluded from the study.

Intervention groups

Intervention group: patients in need of non-surgical root canal retreatment in anterior teeth and single-rooted premolars
Control group: patients in need of non-surgical root canal retreatment in anterior teeth and single-rooted premolars

Main outcome variables

Pain level after treatment on NRS scale up to one week after treatment
The number of painkillers taken up to one week after the treatment

General information

Reason for update

1- In the previous protocol, teeth with normal peri-apical conditions meant teeth that needed root canal retreatment due to leakage. 2- The treatment protocol of the control group was explained more specifically.

Acronym

IRCT registration information

IRCT registration number: **IRCT20211231053574N1**
Registration date: **2022-12-19, 1401/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-01, 1402/03/11**

Update count: **1**

Registration date

2022-12-19, 1401/09/28

Registrant information

Name

Mohammad Mahdi Kiafar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3342 1330

Email address

m-kiafar@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intra-canal cryotherapy on postoperative pain in single-visit endodontic retreatment: randomized clinical trial

Public title

Effect of intra-canal cryotherapy on postoperative pain in single-visit endodontic retreatment: randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients should be classified as ASA I or ASA II in terms of systemic health The teeth should have no spontaneous pain Teeth with periapical lesions or teeth with clear evidence of leakage.

Exclusion criteria:

Teeth that cannot create a glide path to the apical foramen due to canal blockage or previous treatment errors Patients with chronic periapical abscess, sinus tract, internal or external resorption, periodontal problems Pregnant patients Patients with a history of trauma Patients with Temporomandibular disorders Patients who cannot take NSAIDs Patients who have a history of taking antibiotics, analgesics and anti-inflammatory agents before treatment Patients who smoke more than 10 cigarettes a day

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

46 sealed envelopes are prepared which contain a sheet to determine the patient group. Half of the envelopes belong to the cold therapy group and a half to the control group. The patient randomly chooses an envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Before the treatment, the patient does not know which group he is in, and because of the anesthesia, he does not feel the cold caused by the irrigant during the treatment, and he will not notice his grouping. The person in charge of data collection does not know which group each patient was in. The person responsible for evaluating the data does not know what treatment each group received and only compares the group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of School of Dentistry- Tehran University of Medical Sciences

Street address

Endodontics department, Tehran university of medical sciences school of dentistry, North Kargar

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2022-08-22, 1401/05/31

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.072

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

Post-operative pain after a single visit non-surgical root canal retreatment

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

Post-operative pain on the scale of Numerical Rating Scale

Timepoint

6h-18h-24h-48h-72h-7d

Method of measurement

Numerical Rating Scale on the scale of 0-100

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who undergo non-surgical root canal retreatment in one visit, at the end of the treatment, and before the obturation, the root canals are irrigated with normal saline 2-4 degrees Celsius

Category

Treatment - Other

2

Description

Control group: Patients who undergo non-surgical root canal retreatment under the same standard treatment as the intervention group, so that the only difference between the treatment process of the two groups is the normal saline temperature used for the final cleaning of the canal.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry- Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Kiafar

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Endodontics department, Tehran university of medical sciences school of dentistry, North Kargar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sholeh Ghabraei

Street address

Endodontics department, Tehran university of medical sciences school of dentistry, North Kargar

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+98 912 207 5034

Email

sholehghabraei@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Kiafar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Endodontics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Kiafar

Position

Resident

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Other areas of specialty/work

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

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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

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The amount of pain after treatment, the amount of painkillers consumed, age, sex, type of tooth

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Universities and scientific and industrial institutions

Under which criteria data/document could be used

Using for systematic reviews on the subject or conducting similar research in this field or making related devices to reduce pain after treatment

From where data/document is obtainable

Endodontics department, Tehran university of medical sciences school of dentistry, North Kargar, postal code 1439955991 Mobile phone: 00989106498348 Email: m-kiafar@razi.tums.ac.ir

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

Sending a written request with the mention of the university or institution requesting the information to the above address or via email or WhatsApp to the email or number listed and replying to the request after confirming the identity of the person making the request up to 1 month after receiving the request letter .

Comments