

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1439955991

#### Phone

+98 21 6636 9439

#### Email

m-kiafar@razi.tums.ac.ir

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1439955991

#### Phone

+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

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Mahdi Kiafar

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**Latest degree**

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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**