Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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

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1439955991

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

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Person responsible for scientific inquiries

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Latest degree
Medical doctor
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Person responsible for updating data

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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