

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

comparison of pain scale after single-visit root canal treatment by different temperatures and concentrations of NaOCl in mandibular molars with irreversible pulpitis: Double-blind randomized clinical trial

Protocol summary

Study aim

comparison of pain scale after single-visit root canal treatment by different temperatures and concentrations of NaOCl in mandibular molars with irreversible pulpitis

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 2 on 72 patients. RandList software will be used for randomization.

Settings and conduct

In this study, 72 patients at the endodontics department of Tabriz Dental School who have mandibular molars with irreversible pulpitis, will be selected and will be divided into 6 groups of 12. These groups will vary in terms of detergent concentration and room temperature. After treatment of the mandibular molar root of each group, the effect of detergent concentration and temperature on pain reduction will be investigated.

Participants/Inclusion and exclusion criteria

Inclusion: Systemically healthy patient, Patient age 18-65 years Lack of sensitivity to epinephrine and sodium hypochlorite, No facial paraesthesia, Do not take any painkillers 12 hours before treatment Do not take any medication that interferes with anesthesia, No history of trauma, Absence of pathological envelope during probing Completion of an ethical questionnaire and willingness to participate in the study, Lower molar teeth with irreversible pulpitis Exclusion: No lip anesthesia after 15 minutes of block injection, Pain for no reason before treatment, Pregnancy and lactation, Severe periodontal disease Teeth that can not be isolated with my brush, Calcification of the urethra, Teeth with severe irreparable caries, Use of a specific drug or medication

Intervention groups

Patients requiring treatment of mandibular molars with irreversible pulpitis that has been treated and the effect of sodium hypochlorite at different temperatures and

concentrations on the severity of patients' pain will be investigated.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220108053665N1**

Registration date: **2022-01-24, 1400/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-24, 1400/11/04**

Update count: **0**

Registration date

2022-01-24, 1400/11/04

Registrant information

Name

Hadi mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5965

Email address

mokhtari@tbzmeed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-17, 1400/10/27

Expected recruitment end date

2022-02-14, 1400/11/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparison of pain scale after single-visit root canal treatment by different temperatures and concentrations of NaOCl in mandibular molars with irreversible pulpitis: Double-blind randomized clinical trial

Public title
The effect of using sodium hypochlorite detergent at different temperatures and concentrations on pain intensity after endodontic treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Systemically healthy patient Patient age 18-65 years No hypersensitivity to epinephrine and sodium hypochlorite No facial paraesthesia Do not take any palliatives 12 hours before treatment Do not take any drugs that Anesthesia interferes No history of trauma No pathological envelope during probing Completion of ethical questionnaire and willingness to participate in the study Lower molar teeth with irreversible pulpitis
Exclusion criteria:
No lip anesthesia after 15 minutes of block injection8 Pain for no reason before treatment Pregnancy and lactation Severe periodontal disease Teeth that can not be isolated with a rubberdam Root canal calcification Tooth with severe unrestorable caries Use of a specific drug or narcotic

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
All stages of treatment will be performed in Tabriz Dental School. These 72 people are randomly assigned to the 6 groups mentioned using RandList software. All random numbers are written on a piece of paper. The sheets are folded and placed in a container. For each number, one of the groups is selected. The syringes containing the washing solution are covered with a layer of opaque coating. Each patient chooses a sheet and uses one of the detergents for that patient based on the selected number. Thus, neither the patient nor the researcher is aware of the type of treatment chosen and the study will be double blind.

Blinding (investigator's opinion)
Double blinded

Blinding description
The syringes containing the washing solution are covered with a layer of opaque coating. Each patient chooses a sheet and uses one of the detergents for that patient based on the selected number. Thus, neither the patient nor the researcher is aware of the type of treatment chosen and the study will be double blind. To blind the study, all steps of sodium hypochlorite solution preparation will be performed by a trained assistant who has no role in the clinical process, and to prevent the researcher from feeling the temperature of the washing solutions, an insulating coating will be used on the washing syringes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Central office of Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd
City
Tabriz
Province
East Azarbaijan
Postal code
5165687386
Approval date
2021-12-27, 1400/10/06
Ethics committee reference number
IR.TBZMED.REC.1400.978

Health conditions studied

1

Description of health condition studied
Irreversible pulpitis
ICD-10 code
K04.02
ICD-10 code description
Irreversible pulpitis

Primary outcomes

1

Description

Intensity of pain

Timepoint

Immediately after treatment, 3, 24, 48, 72 hours and 7 days after treatment

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients who have mandibular molars with irreversible pulpitis and are treated with root canal using 1% sodium hypochlorite as a detergent at 40 ° C

Category

N/A

2

Description

Intervention group 2: Patients who have mandibular molars with irreversible pulpitis and are treated with root canal using 0.5% sodium hypochlorite as a detergent at 22° C

Category

N/A

3

Description

Intervention group 3: Patients who have mandibular molars with irreversible pulpitis and are treated with root canal using 0.5% sodium hypochlorite as a detergent at 40 ° C

Category

N/A

4

Description

Intervention group 4: Patients who have mandibular molars with irreversible pulpitis and are treated with root canal using 1% sodium hypochlorite as a detergent at 2.5° C

Category

N/A

5

Description

Intervention group 5: Patients who have mandibular molars with irreversible pulpitis and are treated with root canal using 0.5% sodium hypochlorite as a detergent at 2.5° C

Category

N/A

6

Description

Intervention group 6: Patients who have mandibular molars with irreversible pulpitis and are treated with root canal using 1% sodium hypochlorite as a detergent at 22° C

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontics Department of Tabriz Dental School

Full name of responsible person

Hadi Mokhtari Zanuzi

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Dentistry Faculty of Tabriz, Golgasht Ave, Azadi Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Mokhtari Zanuzi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

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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