

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of sodium Hypochlorite and Super oxidized water on Endodontic postoperative pain in human necrotic single canal tooth (Clinical trial)

Protocol summary

Study aim

Comparison the effect of superoxidized water with sodium hypochlorite on postoperative pain intensity after single root canal treatment on patients in the endodontics department of the School of Dentistry Islamic azad university in 1400-1401

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 70 patients

Settings and conduct

All steps are performed by the first year specialist assistants in Azad Tehran's Dental school. Blinding has been done as a cover among participants and clinical caregivers

Participants/Inclusion and exclusion criteria

Anterior single canal human teeth
Teeth which without internal or external root absorption
Teeth which without calcification
Teeth which without caries in root
Root curvature of teeth Less than 15 degrees
All samples will have mature apex
All samples will have necrotic pulp
The patient of choice should be without systemic disease
The selected tooth has normal apical
All samples will have Sensivity to Percussion
The patient should not use pollen for at least 6 hours before treatment
The patient must be at least 18 years old and at most 65 years old
The patient should not be allergic to lidocaine 1/80,000
Female patients should not be pregnant
The patient should not have Severe periodontal disease
Teeth should not have restoration

Intervention groups

Channel preparation is done with the help of a rotary machine and continuous washing. In channel preparation, all channels are prepared up to file number 40, and in all cases root canal treatment will be performed while maintaining patency. During the canal preparation process, in the first group, 2 ml of 5% sodium hypochlorite solution and in the second group, 2

ml of 50% superoxide water are applied as a rinse by a 30 gauge needle with a side hole.

Main outcome variables

Postoperative pain in case and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220113053707N1**

Registration date: **2022-01-18, 1400/10/28**

Registration timing: **prospective**

Last update: **2022-01-18, 1400/10/28**

Update count: **0**

Registration date

2022-01-18, 1400/10/28

Registrant information

Name

Ehsan Esnaashari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2279 3163

Email address

ehsan_dmd@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-08-11, 1401/05/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of sodium Hypochlorite and Super oxidized water on Endodontic postoperative pain in human necrotic single canal tooth (Clinical trial)

Public title
Effect of sodium Hypochlorite and Super oxidized water on postoperative pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Anterior single canal human teeth will chosen. The sample teeth should not have internal or external root resorption. Teeth which without calcification. After preparing the periapical radiograph, the curvature of the roots will be determined by Schneider method and samples with a curvature of less than 15 degrees will be selected. The selected tooth has no apical lesion. All samples will have mature apex. All samples will have necrotic pulp. .The patient of choice should be without systemic disease. The patient must be at least 18 years old and at most 65 years old .
Exclusion criteria:
Teeth should not have restorations. The patient should not have Severe periodontal disease. Female patients should not be pregnant. The patient should not be allergic to 2% lidocaine . The patient should not use any drugs for at least 6 hours before treatment.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization - Individual- Randomiztioan with closed envelop. Using the rand option of Excel software, the samples will be divided into 4 blocks by complete block randomization method. This process is performed by a person who is not present in the clinical work and follow-up of patients (statistics and methodology consultant) and the type of intervention will be provided to the researcher in envelopes in numbered packages and the researcher will open the lock immediately The type of specialized intervention will be informed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients do not know which solution to brush their teeth with. Clinical caregivers also do not know what detergent they are using.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University Dental Branch Tehran - Iran

Street address

Pasdaran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.146

Health conditions studied

1

Description of health condition studied

Post Operative Pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Postoperative pain in anterior teeth single canal

Timepoint

6h. 12h. 24h. 48h. 72h .7D

Method of measurement

Information form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 35 teeth, all of which have been prepared with the help of a rotary device and up to 40 files, and in all cases, root canal treatment will be performed while maintaining patency. These teeth are rinsed with 50% superoxide water (Khosro Medisa Teb) and 30 gauge needles with side holes.

Category

Treatment - Devices

2

Description

Control group: 35 teeth are prepared in the same way as the intervention group and are rinsed with 5% Sodium Hypochlorite Solution.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Islamic Azad University of Tehran

Full name of responsible person

Amirabbas Moshari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Arash Azizi

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Sarina Payandeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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No.8, Mohammadreza Kousha street, Mirdamad Blvd, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Amirabbas Moshari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Endodontics

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some parts of data related to interventions are possible for sharing

When the data will become available and for how long

Starting 6 months after publication People working in academic or business

To whom data/document is available

People working in academic or business

Under which criteria data/document could be used

Not possible

From where data/document is obtainable

Amirabbas Moshari Email: amirabbas.moshari@gmail.com

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

Contacting with the correspondence and introducing himself receiving the data within 1 month

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

Islamic Azad University

Full name of responsible person

Sarina Payandeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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