Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 canall treatment On patients in the endodontics department of the School of Dentistry Islamic azad university in1400-1401

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)

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+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- Randomizitioan 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

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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

Postoperatrive 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

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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
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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
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@gmailcom
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