

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison the effect of sodium Hypochlorite and Super oxidized water on Endodontic postoperative pain in human 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 98-99

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 100 patients

Settings and conduct

All steps are performed by the students of the 10th term 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 irreversible pulpitis
The patient of choice should be without systemic disease
The selected tooth has acute apical periodontitis
All samples will have Sensitivity 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

The canal preparation will be done by Step Back technique
The teeth are prepared at least up to file # 30 (MAF) and maximum 50 Irrigation volume for each canal: 2 ml between each instrument
Over Instrumentation should not occur during root canal treatment
Rubber Dam must be used during root canal treatment
Irrigation technique: Passive by syringe and needle with gauge 27
Control group: It's a group that is wash by sodium

hypochlorite

Main outcome variables

type of irrigation
Inflammatory condition of dental pulp
Severe Periodontal Disease
Sensitivity to Percussion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200517047478N1**

Registration date: **2020-08-20, 1399/05/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-20, 1399/05/30**

Update count: **0**

Registration date

2020-08-20, 1399/05/30

Registrant information

Name

Sohrab Tour Savadkouhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2611 5198

Email address

s_savadkouhi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-10-21, 1399/07/30

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 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 Teeth which without caries in root Root curvature of teeth Less than 15 degrees All samples will have mature apex All samples will have irreversible pulpitis The patient of choice should be without systemic disease. The selected tooth has acute apical periodontitis. 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. The target teeth should not have Sensitivity to Percussion

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: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization - Individual- Randomiztioan with closed envelop. each volunteer after meeting the inclusion criteria, randomly allocated by choosing the envelops containing special code which correlates to special irrigation solution in past.

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

Ethics committee of Azad Tehran University of Medical Sciences

Street address

Pasdaran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-07-28, 1399/05/07

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.040

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

Postoprative 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: Teeth that are rinsed with superoxide water50%(khosro medisa teb)(KMT)

Category

Treatment - Devices

2**Description**

Control group: Teeth that are rinsed with superoxide water 1%.

Category

Treatment - Devices

Recruitment centers1**Recruitment center****Name of recruitment center**

Dental School of Islamic Azad University of Tehran

Full name of responsible person

Dr. Sohrab Tour Savadkouhi

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Khosro medisa Teb

Full name of responsible person

Mrs .Khanban

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Dental branch of Tehran Azad University of Medical

Sciences

Proportion provided by this source

5

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

2**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

90

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

Seyed Amirmasoud Mousavi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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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

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

Sohrab tour savadkouhi Email: s_savadkouhi@yahoo.com

Mobile: 00989123803561

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