Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

effect of smear layer removal on postoperative pain in necrotic teeth with chronic apical periodontitis

Protocol summary

Study aim
the effect of smear layer removal on postoperative pain in necrotic teeth with chronic apical periodontitis

Design
Using the Rand option of Excel software, the samples will be divided into 4 blocks by Complete Block Randomization method. The type of intervention is in numbered sealed envelopes and will be provided to the researcher.The researcher will open the envelope immediately before starting work and will be informed about the type of specialized intervention. The study is single blinded.

Settings and conduct
this intervention is performed by 9th semester students of Tehran Azad Dental School

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range 18 to 60 years, good health (ASA I - ASA II) will be determined through medical history. Tooth inclusion criteria: maxilla and mandible single canal teeth no response to vital tests, no sensitivity to percussion, no history of pervious endodontic treatment that have chronic apical periodontitis with periapical index between 3 to 5. Exclusion criteria: People outside the age group of 18 to 60 years, pregnant, with systemic disease, history of allergy or toxic reaction to anesthesia and usage of analgesic drug within 6 hours before endodontic treatment will be excluded from the study. Tooth exclusion criteria: Multichannel teeth, teeth with a lesion size greater than 8 mm and the presence of Severe Periodontal Disease will be excluded

Intervention groups
Intervention group: In this group of 36 people after preparation by Step Back method and rinsing with 1%sodium hypochlorite, in order to remove smear layer, 5mL of 17% EDTA will be used for 1 minute and then 2mL of 5.25% sodium hypochlorite for 30 seconds. Control group:in this group of 36 people smear layer won't be removed and 2mL of normal saline will be used for final rinsing

Main outcome variables
Postoperative pain in case and control groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200517047478N2**
Registration date: **2021-06-02, 1400/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-02, 1400/03/12**
Update count: **0**

Registration date
2021-06-02, 1400/03/12

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
2021-05-31, 1400/03/10

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of smear layer removal on postoperative pain in necrotic teeth with chronic apical periodontitis

Public title

effect of smear layer removal on postoperative pain in necrotic teeth with chronic apical periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with ASA1- ASA2 necrotic single canal teeth in maxilla and mandible are chosen teeth should not have sensitivity to percussion teeth should have chronic apical periodontitis with periapical index 3 to 5 patients must be between 18 and 60 years old teeth should not have internal or external root resorption root curvature should be less than 30 degrees

Exclusion criteria:

patients who are less than 18 years old or more than 60 yeas old pregnant women patients with systemic diseases patients with history of allergic reaction to local anesthesia The patient should not use any drugs for at least 6 hours before treatment. multi canal teeth teeth with more than 8mm lesion size teeth with severe periodontal disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

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)

Single blinded

Blinding description

patients do not know which intervention is being performed on them

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

2021-05-22, 1400/03/01

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.018

Health conditions studied

1

Description of health condition studied

postoperative pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Postoperative pain in single canal teeth

Timepoint

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

Method of measurement

information form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group of 36 people after preparation by Step Back method and rinsing with 1%sodium hypochlorite, in order to remove smear layer, 5mL of 17% EDTA will be used for 1 minute and then

2mL of 5.25% sodium hypochlorite for 30 seconds

Category

Treatment - Other

2

Description

Control group: in this group of 36 people smear layer won't be removed and 2mL of normal saline will be used for final rinsing.

Category

Treatment - Other

Recruitment centers

1

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 sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Arash Azizi

Street address

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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

Azin Pourmohammad

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

Dr. Sohrab Tour Savadkouhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Azin Pourmohammad

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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1956819111

Phone

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Email

Azinpd1@gmail.com

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

6 months after publication

To whom data/document is available

people who work at university

Under which criteria data/document could be used

not possible

From where data/document is obtainable

Sohrab tour savadkouhi Email: s_savadkouhi@yahoo.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