

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 previous 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 years 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

**Street address**

pasdaran

**City**

tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

S\_savadkouhi@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr.Arash Azizi

**Street address**

tehran

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**Province**

Tehran

**Postal code**

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**Phone**

+98 21 2256 4571

**Email**

S\_savadkouhi@yahoo.com

**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

**Street address**

pasdaran

**City**

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**Province**

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**Postal code**

1956819111

**Phone**

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**Email**

azinpd1@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Sohrab Tour Savadkouhi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Pasdaran

**City**

tehran

**Province**

Tehran

**Postal code**

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**Phone**

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**Email**

s\_savadkouhi@yahoo.com

## 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

**Street address**

tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1956819111

**Phone**

+98 21 2256 4571

**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**