

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of the effect of two type of anti-hypersensitivity toothpastes on oral health related quality of life in people with dentin hypersensitivity

#### Protocol summary

##### Study aim

Comparison of the effect of two anti-allergic toothpastes in people with dentine sensitivity

##### Design

Double-blind clinical trial, with parallel groups, randomized, phase 3 on 60 people

##### Settings and conduct

This study is a randomized clinical trial on 60 male and female patients referred to the periodontics department of the Kurdistan Dental school. Patients with symptoms of dental sensitivity and pain to heat and pressure tests are followed by scaling and root planing (SRP). Patients are divided into two groups of 30 people. The first group uses antisenstivity toothpaste containing alphapinene and the second group uses antisenstivity toothpaste containing potassium nitrate. Patients can be asked to use toothpaste twice a day for 1 minute each time for 4 weeks.

##### Participants/Inclusion and exclusion criteria

Entry conditions : patients aged 18-55 years, perform scaling and root planing treatment (SRP) for at least two teeth with dentin hypersensitivity with symptoms of cervical recession, abrasion or erosion. exit conditions: history of allergy, periodontal treatment in the past 6 months, pathology in the oral cavity, chronic systemic disease, teeth with dental sensitivity with more than 1 degree, extensive restorations or defects or prosthetic veneers, irreversible pulp inflammation, enamel cracks or caries, removable partial denture base teeth (RPD), people who receive anti\_epileptic, anti\_histamine, anti\_depressant, sedative, anti\_inflammatory or painkillers. pregnant or lactating women, any anti\_allergic substances in the last 3 months.

##### Intervention groups

Patients are randomly divided into two groups. (A: anti\_hypersensitivity toothpaste containing alphapinene and anti\_hypersensitivity toothpaste containing potassium nitrate)

#### Main outcome variables

cervical recession, Tooth sensitivity, pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220726055559N2**

Registration date: **2023-01-25, 1401/11/05**

Registration timing: **retrospective**

Last update: **2023-01-25, 1401/11/05**

Update count: **0**

##### Registration date

2023-01-25, 1401/11/05

##### Registrant information

##### Name

Shabnam Khalifehzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3362 2260

##### Email address

shabnam.kh63ii@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-20, 1401/09/29

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of two type of anti-hypersensitivity toothpastes on oral health related quality of life in people with dentin hypersensitivity

**Public title**

Comparison of the effect of two type of anti-hypersensitivity toothpastes in people with dentin hypersensitivity

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

People with dentin sensitivity caused by cervical recession, erosion or abrasion Conducting srp treatment for patients with dentin sensitivity before starting the study Patients have at least two teeth with dentine sensitivity with symptoms of cervical recession or erosion or abrasion or gingival recession.

**Exclusion criteria:**

Extensive pathology in the oral cavity History of allergy to compounds in toothpaste Performing any periodontal treatment in the last 6 months Chronic systemic disease (coagulative diseases, kidney disease, diabetes and any other disease that affects a person's periodontal condition). Teeth with tooth sensitivity with more than 1 grade of looseness Teeth with dental sensitivity with extensive restoration or defect or with prosthetic cover Teeth with dental sensitivity suspected of irreversible pulp inflammation, enamel cracks or decay Movable partial denture base tooth (RPD) People who take antiepileptic, antihistamine, anti-depressant, sedative, anti-inflammatory or analgesic drugs they receive. Pregnant and lactating women Persons participating in the same study or treated that during the last three months, any anti-inflammatory product have received tooth sensitivity.

**Age**

From **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The purpose of block randomization is that equal number of participants enter the intervention and control groups. The size of each block is 30 people. In this way, one type of hypoallergenic toothpaste is assigned to the first block and another type to the second block to be.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

anti\_hypersensitivity toothpaste containing alaphapainen and anti\_hypersensitivity toothpaste containing potassium nitrate are named with two letters B&A and will be given to two equal groups of patients. The patients are selected with the minimum entry criteria. There are 30 patients in each group. It will be fully explained to the patients. Written informed consent will be obtained from the patients. The patients will be selected by sampling based on the entry criteria and will be randomly divided into two equal groups. Group A is toothpaste containing anti-allergic contains potassium nitrate and the group will use toothpaste containing alaphapainene. Participants and health personnel will not know the type of toothpaste.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Science

**Street address**

Kurdistan University of Medical Science, Pasdaran Ave

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

661713446

**Approval date**

2022-12-19, 1401/09/28

**Ethics committee reference number**

IR.MUK.REC.1401.303

**Health conditions studied****1****Description of health condition studied**

dentine hypersensitivity

**ICD-10 code**

K03.89

**ICD-10 code description**

sensitive dentine, Other specified diseases of hard tissues of teeth

**Primary outcomes**

## 1

### Description

dentine hypersensitivity

### Timepoint

30 day

### Method of measurement

Using the VAS index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: They receive anti\_hypersensitivity toothpaste containing alphapinene.They use toothpaste twice a day for 30 days for one minute each time

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: They receive anti\_hypersensitivity toothpaste containing potassium nitrate.They use toothpaste twice a day for 30 days and for one minute each time.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kurdistan University of Medical Sciences

##### Full name of responsible person

raefe ghodsi

##### Street address

Kurdistan University of Medical Sciences,Pasdaran Ave

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## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

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#### Full name of responsible person

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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

Sanandaj University of Medical Sciences

#### 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

Sanandaj University of Medical Sciences

##### Full name of responsible person

raefe ghodsi

##### Position

dentistry student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

### Contact

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Specialist

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## Person responsible for updating data

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**Position**

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**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available