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 antisensitivity toothpaste containing alphapinene and the second group uses antisensitivity toothpaste containing potassium nitrate.Patients can be asked to use toothpaste twice a day for1minute each time for 4 weeks.

Participants/Inclusion and exclusion criteria
Entry conditions : patients aged 18-55 years, perform scaling and root planig treatment(SRP)for at least two teeth with dentinhypersensitivity with symptoms of cervical recession,abrasion or erosion.exit conditions:history of allergy,periodontal treatment in the past 6 month,pathology in the oral cavity,chronic systemic disease,teeth with dentalsensitivity with more than1degree, extensive restorations or defects or prosthetic veneers,irreversible pulp inflamattion,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 womens,any anti_allergic substances in the last 3 month.

Intervention groups
Patients are randomly divided into two groups.(A:anti_hypersensitivity toothpaste containing alphapinene and anti_hypersensitivity toothpaste containing potasium 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 alphapainen and anti_hypersensitivity toothpaste containing potasium 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 alphapinene. 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
City
sanandaj
Province
Kurdistan
Postal code
661713446
Phone
+98 87 3366 4645
Email
raefehgh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Maleki
Street address
Pasdaran Ave
City
Sanandaj
Province
Kurdistan
Postal code
661713446
Phone
+98 87 3366 4645
Email
Maleki@muk.ac.ir
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
Street address
No 20, Golestan Alley, Bostan Ave, Baharan
City
Sanandaj
Province
Kurdistan
Postal code
6617834447
Phone
+98 87 3377 1939
Email
raefehgh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
shabnam khalifezadeh

Position
Associate Profesosr

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
No 5,Shaghayegh Alley,Lotfi Ave,Shalman Blvs,Sanandaj City

City
Sanandaj

Province
Kurdistan

Postal code
6617975413

Phone
+98 87 3362 2260

Email
Shabnam.kh63ii@gmail.com

Person responsible for updating data

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

Street address
No 20, Gollestan Alley, Bostan Ave, Baharan Town, Sanandaj City

City
Sanandaj

Province
Kurdistan

Postal code
66 1783 4447

Phone
+98 87 3377 1939

Email
raefehgh@gmail.com

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