

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparing the effectiveness of two types of whitening toothpastes in inhibiting dental stain

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the effectiveness of two types of whitening toothpastes in inhibiting dental stain

Last update: **2023-11-12, 1402/08/21**

Update count: **0**

Design

Double-blind clinical trial, with parallel groups, randomized, phase 3 on 40 people

Registration date

2023-11-12, 1402/08/21

Settings and conduct

This study is a randomized clinical trial on 40 dental students of the Kurdistan University of Medical Sciences. The patients have dental stain . The patients are selected according to the entry and exit criteria. The patients are divided into two groups of 20 people. The first group received whitening toothpaste containing hydrated Silica and whitening toothpaste containing alphapinene were given to the second group and the patients were asked to use the toothpaste twice a day in the morning and at night for two minutes each time for 6 weeks. Then a index that includes a Numerical grading is 3-0 used to measure the intensity and location of the stain

Registrant information

Name

Shabnam Khalifehzadeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-08, 1402/08/17

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Participants/Inclusion and exclusion criteria

Having at least 4 anterior teeth and premolars with stain and without restoration, caries and removable orthodontic appliance or removable and fixed prosthesis
Plaque index below 20% and absence of periodontitis

Intervention groups

patients are randomly divided in two groups.(A is whitening toothpaste containing hydrated silica and B is whitening toothpaste containing alphapinene)

Main outcome variables

dental stain

General information

Scientific title

Comparing the effectiveness of two types of whitening toothpastes in inhibiting dental stain

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220726055559N4**

Registration date: **2023-11-12, 1402/08/21**

Public title

comparing of two types of whitening toothpaste

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least 4 anterior teeth and premolars with stain and without restoration and caries without orthodontic appliance or removable and fixed prosthesis

Exclusion criteria:

systemic diseases pregnancy any restorative treatment and bleaching

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyst

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The purpose of block randomization is that equal number of participants enter the intervention and control groups. In this study, randomization is done using Excel software. In this way, at first, the desired blocks (intervention and control group) will be selected with three-digit codes (one English letter and two numbers) for each person, and then random selection will be done using the Rand between command. The size of each block is 20 people. In this way, one type of whitening toothpaste is assigned to the first block and another type to the second block.

Blinding (investigator's opinion)

Double blinded

Blinding description

whitening toothpaste containing alphasalicylic acid and whitening toothpaste containing hydrated silica 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 20 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 whitening toothpaste containing hydrated silica and the group B will use toothpaste containing alphasalicylic acid. 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

Pasdaran Ave, Kurdistan University of Medical Science

City

Sanandaj

Province

Kurdistan

Postal code

661713446

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.MUK.REC.1402.113

Health conditions studied

1

Description of health condition studied

dental stain

ICD-10 code

K03.6

ICD-10 code description

Deposits [accretions] on teeth

Primary outcomes

1

Description

dental stain

Timepoint

measurement dental stain at the beginning of the study, after 28 days and 42 days.

Method of measurement

We determine the intensity and location of the stain by using Loben's numerical index, which is 0-3

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A They received whitening toothpaste containing silica hydrate. They used the toothpaste on the toothbrush twice a day for 42 days for two minutes each time.

Category

Treatment - Drugs

2

Description

Intervention group: B They receive whitening toothpaste containing alphapinene. They use the toothpaste twice a day for 42 days, for two minutes each time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan University of Medical Sciences

Full name of responsible person

Shaghayegh Khoshnama Bahrami

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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

Shaghayegh Khoshnama Bahrami

Position

Dental Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Latest degree

Specialist

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Dentistry

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Person responsible for updating data

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Full name of responsible person

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Position

Dental Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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