

# 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

##### 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

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 alphasainen 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 alphasainene. 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, Kurdsitan 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 alaphinene. 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

##### Street address

Kurdistan University of Medical Sciences,Pasdaran Ave

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

661713446

##### Phone

+98 87 3366 4645

##### Email

shaghayegh.khb@yahoo.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

Shaghayegh Khoshnama Bahrami

#### Position

Dental Student

#### Latest degree

A Level or less

#### Other areas of specialty/work

Dentistry

#### Street address

No 91,Bahar building , Baharan

#### City

Sanandaj

#### Province

Kurdistan

#### Postal code

6617738168

#### Phone

+98 87 3377 1661

#### Email

shaghayegh.khb@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Sanandaj University of Medical Sciences

#### Full name of responsible person

Shabnam Khalifehzadeh

#### 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

**Email**

shaghayegh.khb@yahoo.com

**Person responsible for updating data**

**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

**Street address**

No 91,Bahar building ,Baharan

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617738168

**Phone**

+98 87 3377 1661

**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