

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study on effect of Alpha danan and sensodyne toothpastes on pH salivary chang.

Protocol summary

Study aim

The aim of this study was to compare the effect of alpha and Danes toothpaste on salivary pH change.

Design

Double-blind, randomized, phase 4 clinical trial on 40 patients, even and odd numbers were used for randomization

Settings and conduct

Wait 5 minutes for the samples and then pour 5 cc of the collected spitting saliva into the laboratory tube. In the first intervention, 2 cc of toothpaste is given to the samples. After the allotted time, people are asked to rinse their mouths with water. Individuals are asked to collect their saliva for five minutes and then drain it into a laboratory tube. people are given 72 hours to have a normal diet. At this stage, observing all the aspects and instructions provided, for the second time, we measure the pH of the saliva of the mouths of people in groups one and two before brushing. Then, by applying considerations, the second intervention is performed

Participants/Inclusion and exclusion criteria

Inclusion criteria: are among the students of Sanandaj Dental School. have completed the consent form. Be in the age group of 35-38 years. should not be affected by systemic diseases that affect saliva. have not recently undergone radiotherapy. Do not use antihypertensive drugs and antibiotics continuously. Exclusion criteria: are allergic to toothpaste compounds. If you do not participate in the second stage of intervention.

Intervention groups

People in group one use alpha toothpaste in the first intervention and Sensodyne toothpaste in the second intervention. People in group 2 use Sensodyne toothpaste in the first intervention and alpha toothpaste in the second intervention. First, to remove food debris, they rinse their mouths with water several times, then both groups are given 2 cc of toothpaste in each intervention to scrub for 3 minutes. After 72 hours, the second intervention is performed.

Main outcome variables

Salivary pH change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201213049704N1**

Registration date: **2021-04-11, 1400/01/22**

Registration timing: **prospective**

Last update: **2021-04-11, 1400/01/22**

Update count: **0**

Registration date

2021-04-11, 1400/01/22

Registrant information

Name

Ramazan Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-04, 1400/02/14

Expected recruitment end date

2021-05-09, 1400/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on effect of Alpha danan and sensodyne toothpastes on pH salivary chang.

Public title

A comparative study on effect of Alpha danan and sensodyne toothpastes on pH salivary chang.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Samples are among the students of Sanandaj Dental School. Samples complete the consent form. Be in the age group of 35-18 years. . The specimens do not have systemic diseases that affect saliva, such as diabetes, asthma, kidney and liver failure, epilepsy, blood and glandular disorders. . Samples do not have removable orthodontic appliances and prostheses. Samples have not recently undergone radiotherapy. Samples are not smokers. Samples Do not use antihypertensive drugs and antibiotics regularly.

Exclusion criteria:

1. Samples are allergic to toothpaste compounds. 2. If you do not participate in the second stage of intervention.

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each participant will participate in the first and second phases of the intervention and will use a specific type of toothpaste in each intervention.

Randomization (investigator's opinion)

Randomized

Randomization description

The names of the people who are eligible to enter the research are written on separate cards and we put them all in a pot, then the people who are pulled out one by one, form the research samples that Simple random forms are divided into groups one and two, for this purpose, according to the number of sample people, we put cards in the pot on which we write the number one and the other half number two, and the people based on their card number in There are one or two groups (depending on the type of study (cross-clinical trial), each person is measured against himself / herself, so there is no need to match the groups in terms of age and gender).

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding participants: To eliminate bias, we use double-blind, for this purpose, two types of toothpaste are poured into similar white tubes so that it is not possible to identify the type of toothpaste by the samples and the amount of error and Minimize orientation. Outcome Evaluation Blindness: The pH measurement with a pH meter is performed by a research student who has acquired the necessary skills to do so and is unaware of the type of toothpaste used by the samples.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics committee of kurdestan University of Medical Sciences

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Kurdistan Besat Medical Sciences Dormitory, Above Jam Jam Crossroads, Adab Street

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Kurdistan

Postal code

6617939438

Approval date

2020-02-16, 1398/11/27

Ethics committee reference number

IR.MUK.REC.1398.280

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

Dental caries

ICD-10 code

K02.9

ICD-10 code description

Dental caries, unspecified

Primary outcomes**1****Description**

Saliva pH

Timepoint

In the first intervention: before brushing with toothpaste

and after brushing with toothpaste. 72 hours later, perform the second intervention: before brushing with toothpaste and after brushing with toothpaste

Method of measurement

PH meter model pH meter BASIC 20+

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Group I (half of the study volume, which uses alpha toothpaste in the first intervention and toothpaste under the brand name Sensodyne in the second intervention (72 hours later)). Group two (half of the study volume that used toothpaste under the brand name Sensodyne in the first intervention and alpha toothpaste in the second intervention (72 hours later).)

Category

Other

2

Description

Control group: According to the type of study (crossover clinical trial), each person is measured against himself. In other words, the intervention groups at each stage are their control group for the next intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan Dental School of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mohammad Rastegar Khosravi

Position

Assistant Professor

Latest degree

Specialist

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable