

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigation of herbal toothpaste containing *Salvadora persica*, Propolis and *Stevia rebaudiana* on group of *Streptococcus mutans* bacteria and its comparison with a common chemical toothpaste.

Protocol summary

Age , Gender , Salivary bacteria , Toothpaste

Study aim

Comparison of plant toothpaste containing *Salvadora persica* extract, Propolis and *Stevia rebaudiana* with a common chemical toothpaste on the amount of bacteria in *Streptococcus mutans* saliva

Design

Clinical trial with two groups including chemical or herbal toothpaste, with parallel groups, 70 patients

Settings and conduct

In this clinical trial study, we first perform scaling and health education for all participants, who are 70 in Qom Dental School. After preparing a non-stimulated saliva sample from all participants, we randomly divide the participants into two groups of 35 people. Participants used toothpaste for 14 days, after which a saliva sample was taken to test for *Streptococcus mutans*. Finally, the number of colonies of *Streptococcus mutans* in saliva for both groups of toothpaste will be examined by Mann-U-Whitney and Wilcoxon tests.

Participants/Inclusion and exclusion criteria

Participants in the study should have normal periodontium and no systemic disease or a history of antibiotics, anti-inflammatory drugs, and periodontal treatment during the past 3 months. Candidates must be 18 years of age or older and must have at least 20 teeth. People who are definitely allergic to the herbal ingredients in toothpaste. People with orthodontic appliances or fixed or removable prostheses will be excluded from smoking, pregnant and lactating women.

Intervention groups

Group 1: Prophylaxis and scaling and preparation of saliva sample and use of herbal toothpaste for two weeks and then re-preparation of saliva sample
Group 2: Prophylaxis and scaling and preparation of saliva sample and use of chemical toothpaste for two weeks and then re-preparation of saliva sample

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210604051492N1**

Registration date: **2021-07-08, 1400/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-08, 1400/04/17**

Update count: **0**

Registration date

2021-07-08, 1400/04/17

Registrant information

Name

seyed mohammad amin Motevallia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3770 0094

Email address

aminmotevallia@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of herbal toothpaste containing *Salvadora persica*, *Própolis* and *Stevia rebaudiana* on group of *Streptococcus mutans* bacteria and its comparison with a common chemical toothpaste.

Public title

Effect of herbal toothpaste containing *Salvadora persica*, *Própolis* and *Stevia rebaudiana* on group of *Streptococcus mutans* bacteria

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Have normal periodontium Have no systemic illness or history of antibiotics, anti-inflammatory drugs and periodontal treatment in the past 3 months Have at least 20 teeth People who are definitely allergic to the herbal ingredients in toothpaste.

Exclusion criteria:

Smoker people Pregnant people Breastfeeding people People have fixed or removable orthodontics and dental Prosthesis appliance

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

More than 1 sample in each individual

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

Saliva samples are prepared from each person at the beginning and end of the study

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

Dentistry faculty of Qom university of medical science
saheli ave, bajak blvd

City

Qom

Province

Ghorm

Postal code

3713649373

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.MUQ.REC.1400.033

Health conditions studied

1

Description of health condition studied

The amount of bacteria in the group of *Streptococcus mutans* saliva

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of bacteria in the group of *Streptococcus mutans* saliva

Timepoint

At the beginning of the study and day 14 after consuming toothpaste.

Method of measurement

The number of colonies formed in each plate is calculated by CFU method.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Herbal toothpaste, twice a day for 14 days , Albodent herbal toothpaste factory of Armaghan Salamat Alvand Faraz Company

Category

Prevention

2

Description

Intervention group: Chemical toothpaste, used twice a day for two weeks, use a common type of chemical toothpaste produced in Iran that has a standard

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom faculty of Dentistry, Medical Sciences

Full name of responsible person

Dr. Mehrdad Kahvand

Street address

Qom faculty of Dentistry, Saheli ave, Bajak blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr. Ayda Mehdipour

Street address

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info@muq.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghoum University of Medical Sciences

Proportion provided by this source

10

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

Person responsible for general inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Seyed Mohammad Amin Motevallia

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Merdad Kahvand

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Start access to data September 1400

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The information obtained from this study is only permissible to evaluate the effectiveness of the components of herbal toothpaste on the amount of saliva bacteria available to individuals.

From where data/document is obtainable

Saheli St., Qom Dental School, Vice Chancellor for Research Phone: 02537700094

What processes are involved for a request to access data/document

Request to the Vice Chancellor for Research of the School of Dentistry and then receive within a week

Comments

It should be noted that the data obtained from this study have no commercial benefit