

# 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

Ghous

## 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

**City**

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**Province**

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**Postal code**

3713649373

**Phone**

+98 25 3770 0094

**Email**

aminmotevallia@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Dr. Ayda Mehdipour

**Street address**

Qom faculty of Dentistry, Saheli ave, Bajak blvd

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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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Qom School of Dentistry, Saheli ave, Bajak blvd

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**Province**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Merdad Kahvand

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

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**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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**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