

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of *Salvadora Persica* on periodontal indices in patients with generalized gingivitis

#### Protocol summary

##### Study aim

Evaluation of *Salvadora Persica* herbal toothbrush in removing plaque and improving periodontal indices compared to conventional toothbrush in patients with generalized gingivitis

##### Design

Clinical trial with control group, parallel groups, double-blind, randomized, and on 50 patients.  
Site: [www.randomization.com](http://www.randomization.com) is used for randomization.

##### Settings and conduct

The study site is Mashhad Dental School. First, the periodontal indices of the subjects are measured and then scaling is performed for them. The subjects are then randomly divided into two groups, one given a *Salvadora Persica* herbal toothbrush and the other a regular toothbrush. Both groups are taught how to brush efficiently. After 4 weeks of using these devices, patients' periodontal indices are measured again, and compared with before the intervention as well as between the two methods and analyzed statistically. They are also blind assessors, and statistical analysts.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with generalized gingivitis  
exclusion criteria : 1.Taking anti-inflammatory drugs during the study 2.Systemic diseases such as diabetes and heart disease 3.Addiction and smokers 4.Patients taking immunosuppressive drugs 5.Pregnancy and lactation 6.Advanced gum disease 7.Take antibiotics at least 14 days before and after the study period 8.Severe dental malocclusion and patients receiving orthodontic treatment 9.Sjogren's syndrome

##### Intervention groups

In the intervention group, after measuring periodontal indices and scaling, *Salvadora Persica* herbal toothbrush is given to the intervention group, which does not require the use of toothpaste. In the control group, after measuring periodontal indices and scaling, the control group is given a regular toothbrush (one type of brand) with toothpaste .

#### Main outcome variables

Plaque index; gingival index; bleeding on probing; packet depth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210426051084N1**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

##### Registration date

2022-05-23, 1401/03/02

##### Registrant information

##### Name

Hamed Hokmabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3270 6182

##### Email address

[hokmabadh951@mums.ac.ir](mailto:hokmabadh951@mums.ac.ir)

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-25, 1401/02/05

##### Expected recruitment end date

2022-05-31, 1401/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of Salvadura Persica on periodontal indices in patients with generalized gingivitis

**Public title**  
The effect of Salvadura Persica on periodontal indices in patients with generalized gingivitis

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients suffering generalized gingivitis  
**Exclusion criteria:**  
Systemic diseases such as diabetes and heart disease  
Addiction and smokers  
Patients taking immunosuppressive drugs  
Pregnancy or lactation  
Advanced gum disease  
Take antibiotics at least 14 days before and after the study period  
Severe dental malocclusion and patients receiving orthodontic treatment  
Taking anti-inflammatory drugs during the study  
Sjogren's syndrome

**Age**  
From **18 years** old to **55 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block randomization using the site [www.randomization.com](http://www.randomization.com). For equal gender distribution, 25 people, including women, are randomly divided into two groups (12 and 13 people) by the randomization site, and to see which group to use what type of toothbrush, We choose between the two groups in a simple random way. Now the numbers obtained from the site For example, numbers 1.6.7.10.11.12.13.14.15.17.21.22.23 (The numbers indicate the order of arrival of the clients). For a group And the numbers 2,3,4,5,5,8,9,16,18,19,20,24,25, we consider for the other group. now we do the same for the male group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Statistical Analyst Blinding Method: The results of each group are divided into two groups with the letters A and B and it is not known which group received which type of toothbrush. Clinical evaluator blinding method (examiner and measurement of required indicators): Toothbrushes are placed in closed packages and its contents are not visible from the outside, it is given to the participants in

the study. And the evaluator does not know what type of toothbrush the person receiving received.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committes of School of Dentistry- Mashhad university of medical sciences

##### Street address

At the beginning of Vakilabad blvd., in front of Mellat Park, School of Dentistry , mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91177948909

#### Approval date

2022-03-07, 1400/12/16

#### Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1400.151

## Health conditions studied

### 1

#### Description of health condition studied

Generalized gingivitis

#### ICD-10 code

K05.10

#### ICD-10 code description

Chronic gingivitis, plaque induced

## Primary outcomes

### 1

#### Description

Plaque index

#### Timepoint

Initially studied and 4 weeks after the initial examination

#### Method of measurement

Silness and Loe plaque index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: *Salvadora Persica* herbal toothbrush (Contains four replaceable heads). Duration of use: four weeks and twice a day, the method of brushing is the bass technique; How to use: the toothbrush head is replaceable and each participant must change the toothbrush head after one week of use; In the first use of the new head, you should chew the new head to open the strands of the plant and then brush your teeth.

#### Category

Treatment - Other

### 2

#### Description

Control group: toothbrush with toothpaste; duration of use: four weeks and twice a day, the method of brushing is the bass technique; the type of toothbrush used is Signal Company's ultra reach toothbrush and the toothpaste used is close-up toothpaste.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad Dental School

##### Full name of responsible person

Naser Sargolzaie

##### Street address

Mashhad, at the beginning of Vakilabad Boulevyvard, in front of Mellat Park,

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3806 7100

##### Email

SargolzaieN@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Majid Ghayour Mobarhan

##### Street address

Khorasan Razavi, Mashhad, Daneshgah St., next to Hoveyzeh Cinema, Ghorashi Building, Deputy of

Research and Technology

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

GhayourM@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

naser sargolzaie

##### Position

Associate Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

At the beginning of Vakilabad blvd., in front of Mellat Park

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##### Province

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##### Postal code

9177948959

##### Phone

0098513806710

##### Email

sargolzaieN@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

**Full name of responsible person**

Naser Sargolzaie

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hamed Hokmabadi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

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**Province**

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**Postal code**

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**Fax**

**Email**

HokmabadH951@mums.ac.ir

**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**

Not applicable

**Data Dictionary**

Not applicable