

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 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

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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. 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

9117794809

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 Boulevyrd, in front of Mellat Park,

City

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Razavi Khorasan

Postal code

9177948959

Phone

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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

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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

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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

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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

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