Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Salvadura 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
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Iran (Islamic Republic of)
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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 sciencs

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۱۷۷۹۴۸۹۵۹

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 Bouleryvard, in front of Mellat Park,
City
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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
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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
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

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Name of organization / entity

Mashhad University of Medical Sciences

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Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Hamed Hokmabadi

Position
Student

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Medical doctor

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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