

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the Effectiveness of a Herbal Toothpaste containing *Salvadora Persica*, Propolis and Stevia with a common Chemical Toothpaste on Improving Plaque Index and Gingival Index in Dental Students

Protocol summary

Satisfaction Rate, Plaque Index, Gingival Index

Study aim

Comparison of the Effectiveness of Herbal Toothpaste Containing *Salvadora Persica*, Propolis and Stevia with the common Chemical Toothpaste in Iran on Plaque Index and Gingival Index

Design

Clinical Trial with Two Intervention Groups, with parallel groups, blinded, randomised, 70 patients

Settings and conduct

To Determine the Plaque Index, The Fuchsin Tablet is used on all Supragingival Dental Surfaces and The Amount of Plaque on the Buccal and Lingual Surfaces of all Teeth except the Third Molars will be evaluated. LÖe & sillnes sillnes Index is used to Measure the Gingival Index. Study place: Periodontology department of Qom Dental School

Participants/Inclusion and exclusion criteria

Entry Requirements: Normal Periodontium - No Systemic Diseases - No History of Antibiotics and Anti-Inflammatory Drugs and Periodontal Treatment in the Last 3 Months - Age 18 Years and Older - Having at least 20 Teeth in the Mouth Exit conditions: Orthodontic Appliance - Fixed or Removable Dental Prosthetics - Smokers - Pregnant or Breastfeeding People - People with Definite Allergies to Herbal Ingredients in Herbal Toothpaste

Intervention groups

People are divided into Two Intervention Groups 1 and 2. In both Groups, Scaling and Root Planning and Brusage are performed first, And then Plaque and Gingival Indexes are measured. Then One Group is given Herbal Toothpaste and the other Group is given Chemical Toothpaste. People use their Toothpaste for 14 Days and then the Plaque and Gingival Indexes are measured Again.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210605051494N1**

Registration date: **2021-07-11, 1400/04/20**

Registration timing: **prospective**

Last update: **2021-07-15, 1400/04/24**

Update count: **1**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

Mahdi Dolatkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5520 9664

Email address

dolatkhanimahdi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-16, 1400/04/25

Expected recruitment end date

2021-08-16, 1400/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of a Herbal Toothpaste containing *Salvadora Persica*, Propolis and Stevia with a common Chemical Toothpaste on Improving Plaque Index and Gingival Index in Dental Students

Public title

Comparison of the Effectiveness of a Herbal Toothpaste containing *Salvadora Persica*, Propolis and Stevia with a common Chemical Toothpaste on Plaque Index and Gingival Index

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Normal Periodontium Absence of Systemic Disease No history of Antibiotics, Anti-Inflammatory Drugs and Periodontal Treatments in the last 3 months Age 18 years and Above Having at least 20 Teeth in the Mouth

Exclusion criteria:

Orthodontic Appliance or Fixed and Removable dental Prosthetics Smokers Pregnant and Breastfeeding People People with definite Allergies to Herbal Ingredients in Herbal Toothpaste

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in two Groups by Block Randomization Method. The Size of the Blocks is 4. The Random Order of the Blocks is also done by Throwing Dice from 6 possible Combinations.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this Study, both Patients and Researchers are kept Blind. To Blind Patients, two similar Tubes with the same Color and Taste content are used. In order to Blind the Researcher, The Research Team sticks Labels A and B on the Tubes and The Therapist is Unaware of the Type of Treatment.

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

No. 83, Jahad Daneshgahi Alley, Safashahr St., Qom

City

Qom

Province

Ghous

Postal code

3716993456

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.MUQ.REC.1400.050

Health conditions studied**1****Description of health condition studied**

Plaque Index and Gingival Index

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plaque Index and Gingival Index

Timepoint

Measurement of Plaque Index and Gingival Index before Using Toothpaste (after scaling and Root Planning and Brusage) and 14 Days after Using Toothpaste

Method of measurement

Fuchsin tablet and periodontal probe

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In This Group, After Scaling and Root Planning and Brusage, the Plaque Index and Gingival

Index is Measured First. The Herbal Toothpaste Containing *Salvadora Persica*, Propolis and Stevia is then given to the Patients. After 14 Days of Using Toothpaste, Plaque and Gingival Index is Measured Again.

Category

Prevention

2**Description**

Intervention group: In This Group, After Scaling and Root Planning and Brusage, the Plaque Index and Gingival Index is Measured First. The Common Chemical Toothpaste in Iran is then given to the Patients. After 14 Days of Using Toothpaste, Plaque and Gingival Index is Measured Again.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Qom Dental College

Full name of responsible person

Mahdi Dolatkhani

Street address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Assistant of Qom University of Medical Sciences

Full name of responsible person

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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

Research Assistant of Qom 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**

Ghous University of Medical Sciences

Full name of responsible person

Mahdi Dolatkhani

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

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Mahdi Dolatkhani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No. 44, Yadegar Emam St., Rey Town

City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more Information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available