

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Sep 2026

Evaluation of the effectiveness of toothpaste containing persimmon extract in the treatment of patients with gingivitis

Protocol summary

Study aim

Effectiveness of toothpaste containing persimmon extract in the treatment and reduction of symptoms of gingivitis patients

Design

In this clinical trial, 56 patients by simple randomization divided equally into two groups of drugs (persimmon extract toothpaste), control toothpaste.

Settings and conduct

56 patients with gingivitis from the outpatients referred to dental school, Mashhad University of Medical Sciences, Mashhad, Iran, were randomly assigned to two groups of and were equally divided. Patients are given two groups of non-labeled toothpaste. toothpaste of persimmon is prepared by the pharmacological research center of Medicinal Plants of Mashhad University of Medical Sciences. Then, periodontist evaluated patients one month later. Patients are urged not to use any other toothpaste arbitrarily.

Participants/Inclusion and exclusion criteria

Gingivitis patients

Intervention groups

For each patient, toothpaste two times a day (persimmon extract or control) for 4 weeks is administered. Persimmon extract is prepared by pharmacological research center of medical plants. The indices are evaluated in one month later by periodontist.

Main outcome variables

Gingivitis index, Plaque index, Pocket depth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190406043175N7**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **prospective**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

fatemeh forouzanfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3761 7318

Email address

forouzanfarf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-29, 1401/07/07

Expected recruitment end date

2024-09-28, 1403/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of toothpaste containing persimmon extract in the treatment of patients with gingivitis

Public title

Persimmon extract toothpaste in treatment of gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gingivitis Patients
Exclusion criteria:
Pregnant or lactating women Allergic to oral hygiene products
Age
From **18 years** old to **65 years** old
Gender
Both
Phase
2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial, 56 patients were assigned to the dental faculty with gingivitis. The informed consent was completed and included the study. By using simple randomization method, a number of cards are selected by the researcher as the first group and the same number of cards for the next group. Then, by merging the cards together (by adding the cards), a card is taken out and its allocation is recorded, and that card is returned to the other cards by merging the cards together (by adding the cards). The cards then merge again and another card will have picked up. This process continues to reach a random sequence according to sample size. The patients divided equally into two groups of drugs (toothpaste containing persimmon extract), control toothpaste.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study mouthwash is given to patients non-labeled, and the periodontist is unaware of which toothpaste is given to each group. Few drops of standard edible brown color will be added to the toothpaste of the control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of dentistry school, Mashhad
University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Azadi
Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1400.150

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Gingivitis index

Timepoint

At baseline, and week 4 of the trial.

Method of measurement

Examination by periodontist with periodontal Williams
probe

2

Description

Plaque index

Timepoint

At baseline, and week 4 of the trial.

Method of measurement

Examination by periodontist with periodontal Williams
probe

3

Description

Pocket depth

Timepoint

At baseline, and week 4 of the trial.

Method of measurement

Examination by periodontist with periodontal Williams
probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: toothpaste containing extract of persimmon. For each patient, toothpaste of persimmon extract two times a day for 4 weeks is administered. Persimmon extract is prepared by pharmacological research center of medical plants. The indices are evaluated in one month later by periodontist.

Category

Treatment - Drugs

2

Description

Control group: Control toothpaste two times a day for 4 weeks is administered. The indices are evaluated in one month later by periodontist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Forouzanfar

Street address

Mashhad University of Medical Science, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2000

Email

forouzanfarf@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

Deputy of Research and Technology, Ghorashi Building, next to Hoveyze Cinema, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

ramresearch@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

Fatemeh Forouzanfar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Mashhad University of Medical Sciences, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2538

Email

forouzanfarf@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Forouzanfar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Forouzanfar

Position

Assistant Professor

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Other areas of specialty/work

Medical Pharmacy

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available