

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Study of the effectiveness of persimmon extract on the treatment of patients with gingivitis

Protocol summary

Study aim

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

Design

In this clinical trial, 50 patients by simple randomization divided equally into two groups of drugs (4% persimmon extract), control (0.2% chlorhexidine).

Settings and conduct

50 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 mouthwashes, and the periodontist is unaware of the fact that any mucous membranes received. mouthwash of persimmon is prepared by the pharmacological research center of Medicinal Plants of Mashhad University of Medical Sciences. Then, periodontist evaluated patients in the second week and one month later. Patients are urged not to use any other mouthwashes arbitrarily.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. gingivitis patients 2. All of these patients had at least 21 permanent teeth and no dental calculus

Intervention groups

For each patient, 10 ml of mouthwash two times a day (persimmon extract 4% or chlorhexidine 0.2%(Behsa, Iran)) for 2 weeks is administered. Persimmon extract is prepared by pharmacological research center of medical plants. The indices are evaluated in the second week and one month later by periodontist.

Main outcome variables

Gingivitis index, plaque index, pocket depth, Bleeding on probing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190406043175N1**

Registration date: **2019-07-16, 1398/04/25**

Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**

Update count: **1**

Registration date

2019-07-16, 1398/04/25

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

2019-09-22, 1398/06/31

Expected recruitment end date

2019-12-20, 1398/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of persimmon extract on the treatment of patients with gingivitis

Public title

Persimmon extract in treatment of gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

gingivitis patients All of these patients had at least 21 permanent teeth no dental calculus

Exclusion criteria:**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: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial, 50 patients were assigned to the dental faculty with mild to moderate 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 (4% persimmon extract), control (0.2% chlorhexidine).

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 mouthwash is given to each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2019-04-23, 1398/02/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.001

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, week 2 and week 4 of the trial.

Method of measurement

Examination by periodontist with periodontal Williams probe

2**Description**

plaque index

Timepoint

At baseline, week 2 and week 4 of the trial.

Method of measurement

Examination by periodontist with periodontal Williams probe

3**Description**

pocket depth

Timepoint

At baseline, week 2 and week 4 of the trial.

Method of measurement

Examination by periodontist with periodontal Williams probe

4**Description**

Bleeding on probing

Timepoint

At baseline, week 2 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: mouthwash containing 4% hydroalcoholic extract of persimmon .For each patient, 10 ml of persimmon extract two times a day for 2 weeks is administered. Persimmon extract is prepared by pharmacological research center of medical plants. The indices are evaluated in the second week and one month later by periodontist.

Category

Treatment - Drugs

2

Description

Control group: Chlorheddine 0.2% produced by Behsa Iran Co.For each patient, 10 ml of mouthwash two times a day for 2 weeks is administered. The indices are evaluated in the second week and one month later by periodontist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Fatemeh Forouzanfar

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Mashhad dental school, University Campus, Azadi square, Mashhad, Iran

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<http://dentistry.mums.ac.ir/index.php>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Faculty of medicine, University campus, Azadi square, Mashhad university of Medical sciences, Mashhad, Iran

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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

Dr. Fatemeh Forouzanfar

Position

Assistant professor, Mashhad University of medical sciences

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Gingivitis index, plaque index, pocket depth, Bleeding on probing

When the data will become available and for how long

6 months after publication

To whom data/document is available

Medical universities

Under which criteria data/document could be used

Any evaluation and analysis must be done under the supervision of executor of the project:

From where data/document is obtainable

Sending email to executor of the project:

What processes are involved for a request to access data/document

Sending email to executor of the project and the response up to 1 week

Comments