Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 51 3761 7318

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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
Street address
Faculty of medicine, University campus, Azadi square, Mashhad university of Medical sciences, Mashhad, Iran
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tafaghodiM@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
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 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