Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of toothpaste containing persimmon and Nigella sativa in the treatment of patients with gingivitis

Protocol summary

Study aim
Effectiveness of toothpaste containing persimmon and Nigella sativa extract in the treatment and reduction of symptoms of gingivitis patients

Design
In this clinical trial, 56 patients will be randomly and double-blindly assigned in equal numbers to two groups using a random number table: the intervention group (toothpaste containing persimmon and Nigella sativa extract) and the control group (regular toothpaste).

Settings and conduct
Fifty-six patients with gingivitis, selected from outpatients at the School of Dentistry, Mashhad University of Medical Sciences, were randomly and double-blindly assigned in equal numbers to two groups. Unlabeled toothpaste was provided to patients in both groups. The toothpaste containing persimmon and Nigella sativa extract was prepared by the pharmacological research center of Medicinal Plants of Mashhad University of Medical Sciences. A periodontist will examine the patients one month later. Patients are instructed not to use any other toothpaste on their own during the study period.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gingivitis patients, having at least 18 natural teeth Exclusion criteria: Pregnant or breastfeeding women, and individuals with known allergies to oral hygiene products

Intervention groups
For each patient, toothpaste two times a day (herbal extract or control) for 4 weeks is administered. Persimmon and Nigella sativa 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, Bleeding on probing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190406043175N13**
Registration date: **2025-07-17, 1404/04/26**
Registration timing: **prospective**

Last update: **2025-07-17, 1404/04/26**
Update count: **0**

Registration date
2025-07-17, 1404/04/26

Registrant information

Name
fatemeh forouzanfar
Name of organization / entity
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-09-22, 1404/06/31

Expected recruitment end date
2028-09-21, 1407/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effectiveness of toothpaste containing persimmon and Nigella sativa in the treatment of patients with gingivitis

Public title
Persimmon and Nigella sativa toothpaste for treating 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 with gingivitis were selected from outpatients at the Mashhad School of Dentistry. After obtaining informed consent, the participants were randomly assigned into two groups using simple randomization through a card method. In this method, an equal number of cards labeled with the names of the two study groups (the group receiving Nigella sativa and persimmon extract, and the control group using regular toothpaste) were prepared. The cards were thoroughly mixed, and one card was randomly drawn for each participant. After recording the group corresponding to the selected card, the card was returned to the pool. This process was repeated until all participants were randomly allocated.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, toothpaste will be provided to participants in both groups in unlabeled and visually identical tubes. To ensure similarity in color and prevent participants from distinguishing between the intervention group (receiving toothpaste containing Nigella sativa and persimmon extract) and the control group, a specific amount of edible brown coloring will be added to the control toothpaste to match the color of the herbal toothpaste. Additionally, efforts will be made to match the control toothpaste with the herbal toothpaste in terms of consistency (viscosity), taste, and packaging. Therefore, there will be no noticeable difference between the two toothpastes in terms of color, appearance, taste, method of use, or packaging, and participant-level blinding will be maintained.
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
Faculty of Dentistry, Azadi Square, East Gate of the University Campus
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2025-02-22, 1403/12/04
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1403.187

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
Bleeding on probing
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 and nigella sativa. For each patient, toothpaste of persimmon extract two times a day for 4 weeks is administered. Herbal 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: Regular 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
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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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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
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Person responsible for updating data

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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