

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 2026

Clinical evaluation of Nigella sativa chewing gum on generalized gingivitis

Protocol summary

Study aim

Clinical evaluation of Nigella sativa chewing gum on generalized gingivitis

Design

A randomized, double-blind, placebo-controlled phase 3 clinical trial with parallel groups on 80 patients. Randomization using Randaizaation.com

Settings and conduct

This study will be performed in the Department of Periodontology, Faculty of Dentistry, Mashhad. Patients are randomly assigned to Nigella sativa chewing gum and placebo groups. The patients and the main researcher are unaware of the group assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic generalized gingivitis; Consent to admission to the study; Having at least 18 natural teeth. Exclusion criteria: Smoking history; Inability to attend follow-up meetings.

Intervention groups

Intervention Group: Patients with generalized gingivitis chew black seed extract chewing gum (containing 5% black seed extract) twice a day (once in the morning after breakfast and once at night before going to bed) for 20 minutes in addition to standard treatment. This will continue for 14 days. Placebo Group: Patients with generalized gingivitis chew placebo chewing gum twice a day (once in the morning after breakfast and once at night before going to bed) for 20 minutes in addition to standard treatment. This will continue for 14 days.

Main outcome variables

Plaque Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N21**

Registration date: **2024-11-04, 1403/08/14**

Registration timing: **prospective**

Last update: **2025-07-14, 1404/04/23**

Update count: **1**

Registration date

2024-11-04, 1403/08/14

Registrant information

Name

Vafa Baradaran Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2301

Email address

baradaranrv@mums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2024-11-05, 1403/08/15

Expected recruitment end date

2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of Nigella sativa chewing gum on generalized gingivitis

Public title

The effect of Nigella sativa chewing gum on generalized gingivitis

Purpose

Treatment	
Inclusion/Exclusion criteria	
Inclusion criteria:	Patients with chronic generalized gingivitis Consent to admission to the study Having at least 18 natural teeth Having an average corrected gingival index of all teeth between 1.3 and 2.75 Having the average modified plaque index of all teeth at least 1.5
Exclusion criteria:	Smoking history Inability to attend follow-up meetings Patients receiving other systemic or local antibiotics
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Care provider - Investigator - Data analyser
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	The blocked randomization method is used. The block size will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)-BBAA(2)-BABA(3)-BAAB(4)), which will be 20 blocks according to the sample size of 80. Then, random numbers between 1 and 20 are selected according to the randomization site Randomaization.com, and finally, the treatment allocation list is determined based on the random numbers.
Blinding (investigator's opinion)	Double blinded
Blinding description	Blinding will performed using sealed envelopes. Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethic's committee of Mashhad University of Medical Sciences
Street address	Qurashi Building, Next to Hoveyzeh Cinema, University Street, Mashhad
City	Mashhad
Province	Razavi Khorasan
Postal code	9138813944
Approval date	2024-08-03, 1403/05/13
Ethics committee reference number	IR.MUMS.REC.1403.251
Health conditions studied	
<u>1</u>	
Description of health condition studied	Chronic gingivitis
ICD-10 code	K05.1
ICD-10 code description	Chronic gingivitis
Primary outcomes	
<u>1</u>	
Description	Plaque Index
Timepoint	The beginning of the study and 14 days later
Method of measurement	According to the PI index (0-10; 0 is without plaque, and 3 is the accumulation of a large amount of soft material in the gums, on the teeth, or at the edge of the gums)
Secondary outcomes	
<u>1</u>	
Description	Loe & Silness Gingival Index
Timepoint	The beginning of the study and 14 days later
Method of measurement	According to the Loe & Silness index (0-3; 0 is the normal gums and 3 is the severe inflammation)
Intervention groups	
<u>1</u>	
Description	Intervention group: Patients with generalized gingivitis

chew black seed extract chewing gum (containing 5% black seed extract) twice a day (once in the morning after breakfast and once at night before going to bed) for 20 minutes in addition to standard treatment. This will continue for 14 days. The black seed extract chewing gum will be provided by Daru Azma Rasa Gostar Fartak company.

Category

Treatment - Drugs

2**Description**

Control group: Patients with generalized gingivitis chew placebo chewing gum twice a day (once in the morning after breakfast and once at night before going to bed) for 20 minutes in addition to standard treatment. This will continue for 14 days. The black seed extract chewing gum will be provided by Daru Azma Rasa Gostar Fartak company.

Category

Placebo

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

Clinics affiliated with Mashhad University of Medical Sciences

Full name of responsible person

Dr. Vahid Reza Askari

Street address

Mashhad University of Medical Science, Azadi Square

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9177948564

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Qurashi Building, Next to Hoveyze Cinema,
University Street, Mashhad

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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. Vafa Baradaran Rahimi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ghaeem hospital, Ahmadabad Blvd, Mashhad

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Vafa Baradaran Rahimi

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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