

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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 RandoMaization.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 Randomization.com, and finally, the treatment allocation list is determined based on the random numbers.

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

Blinding will be 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**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

##### **Street address**

Qurashi Building, Next to Hoveyze 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**

### **1**

#### **Description of health condition studied**

Chronic gingivitis

#### **ICD-10 code**

K05.1

#### **ICD-10 code description**

Chronic gingivitis

## **Primary outcomes**

### **1**

#### **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**

### **1**

#### **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**

### **1**

#### **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

**Phone**

+98 51 3800 2000

**Email**

askariv@mums.ac.ir

**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 Hoveyzeh Cinema,  
University Street, Mashhad

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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**

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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Dr. Vafa Baradaran Rahimi

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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