Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Recruitment complete
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

1

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

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

City

Mashhad

Province

Razavi Khorasan

Postal code

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

0095 5138012739

Email

baradaranrv@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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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