Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effect of Nigella sativa oil and placebo supplementation on flow mediated dilation (FMD) and vascular inflammatory biomarkers in subjects with cardiovascular disease risk factors

Protocol summary

Study aim

This clinical trial aims to assess the effect of Nigella sativa oil on flow mediated dilation (FMD) and vascular inflammatory biomarkers in subject with cardiovascular disease risk factors

Design

A single center, randomized, single blinded, controlled clinical trial with a parallel group design and 50 participants evaluating the effect of Nigella sativa oil on vascular function. Stratified block randomization will be employed to assign subject to each of the two groups.

Settings and conduct

Fifty patients with at least one cardiovascular risk factor, referred to Imam Reza (AS) Hospital, will be randomized into two groups, Nigella sativa oil (2 capsules of 500 mg per day) or mineral oil (2 capsules of 500 mg per day) for 8 weeks. Flow mediated dilation and plasma levels of ICAM-1 and VCAM-1 are measured at baseline and after 8 weeks . Patients did not know the type of intervention and the study was single blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Willingness to participate in the study; Age between 20-75 years; Having elevated at least one of cardiovascular disease risk factors(including Dyslipidemia or diabetes mellitus or hypertension or smoking). Exclusion Criteria: Unwillingness to continue participation; BMI> 30; Patients on anticoagulant or nitrates drugs; Consumption of vitamins or minerals supplements during past month; Chronic kidney disease stage 4 or 5, pregnancy.

Intervention groups

Intervention group: receiving 2 capsules of 500 mg Nigella sativa oil daily for 8 weeks. Control group: receiving 2 capsules of 500 mg mineral oil daily for 8 weeks.

Main outcome variables

Flow mediated dilation (FMD); ICAM-1 and VCAM-1 inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201126049495N1**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **prospective**

Last update: **2020-12-10, 1399/09/20**
Update count: **0**

Registration date

2020-12-10, 1399/09/20

Registrant information

Name

Hadi Emamat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5545 0314

Email address

hadiemamat@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Nigella sativa oil and placebo supplementation on flow mediated dilation (FMD) and vascular inflammatory biomarkers in subjects with cardiovascular disease risk factors

Public title

The effect of Nigella sativa oil on vascular function

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Age between 20-75 years Having at least one of cardiovascular disease risk factors (including diabetes, dyslipidemia, hypertension, smoking)

Exclusion criteria:

having BMI>30 Patients on nitrate or anticoagulant drugs Regular consumption (more than once in a week) of vitamins or minerals supplements during past month Chronic kidney disease stage 4 or 5 pregnancy

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly assigned, in a ratio of 1:1, to either Nigella sativa group or placebo group for 8 weeks. Stratified block randomization will be employed to assign subject to each of the two groups. Stratification subdivides patients into those with diabetes or without diabetes and in each stratum, block size of 4-6 will be used with a 1:1 randomization between the two groups in each block, i.e. each block will consist of 2-3 subjects for the intervention group and 2-3 subjects for the placebo group. the predetermined allocation sequence of each block will be based on a computer-generated randomization list. An online program will be used for this purpose (www.randomizer.org). For each stratum, 8 blocks of 4 to 6 will considered and the sequence of patients in each block will be determined using software. Half of numbers in each block will be for the nigella sativa group and the other half for the placebo group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are blinded of the type of supplement they are consuming, but the main investigator who assigns patients to intervention or placebo groups is not blinded. Nigella sativa oil and placebo supplements are given to patients in similar capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Islamic Republic of Iran Army University of Medical Sciences

Street address

The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.AJAUMS.REC.1399.167

Health conditions studied

1

Description of health condition studied

Cardiovascular disease, Hypertension, diabetes, dyslipidemia

ICD-10 code

R94.30

ICD-10 code description

Abnormal result of cardiovascular function study, unspecified

Primary outcomes

1

Description

Flow mediated dilation (FMD)

Timepoint

Baseline and the end of the study

Method of measurement

sonography

Secondary outcomes

1

Description
plasma ICAM-1
Timepoint
Baseline and the end of the study
Method of measurement
ELISA

2

Description
Plasma VCAM-1
Timepoint
Baseline and the end of the study
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Daily consumption of 2 capsules of 500 mg Nigella sativa oil for 8 weeks.
Category
Treatment - Other

2

Description
Control group: Daily consumption of 2 capsules of 500 mg mineral oil for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
The Islamic Republic of Iran Army University of Medical Sciences
Full name of responsible person
Said Hadi
Street address
The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2284
Email
s.hadinu@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Sanaz Zargar Balaye Jame
Street address
address The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
s.hadinu@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice-Chancellor for Research, The Islamic Republic of Iran Army 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
Artesh University of Medical Sciences
Full name of responsible person
Said Hadi
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
City
Tehran

Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2284
Fax
Email
s.hadinu@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Said Hadi
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2284
Fax
Email
s.hadinu@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Said Hadi
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2284
Fax
Email
s.hadinu@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available