

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effects of nigella sativa extract oil supplementation on plasma level of ICAM-1, VCAM-1 , metabolic and oxidative parameters and nutritional status in patients with coronary artery disease

Protocol summary

Study aim

The effect of supplementation of Nigella Sativa oil extract on plasma level of ICAM-1, VCAM-1, metabolic, oxidative and nutritional status in patients with coronary artery disease

Design

A randomized double-blind clinical trial with two-arm parallel groups phase 3 trial with 46 sample size

Settings and conduct

The trial will be conducted at outpatient cardiology clinic of Shahid Madani Heart center affiliated to Tabriz University of Medical Sciences, Iran. All the patients will be screened by an expert cardiologist for eligibility. Those willing to take part in the study will be carefully evaluated with reference to inclusion criteria. Then, they will be requested to sign an informed consent. A third party who is blind to the study will give the sequence extracted from allocation software. After an overnight fasting, blood will be collected and supplements will be provided to the participants. supplementation duration will be 8 weeks.

Participants/Inclusion and exclusion criteria

inclusion criteria: age between 30-65 years, BMI between 25 -45, Proof of 50% stenosis in at least one of the major coronary arteries in angiography, Ability, and willingness to collaborate on the project exclusion criteria: pregnancy or lactation, smoking cigaret or opiates, any background chronic disease

Intervention groups

Intervention group: Patients in this group will receive Nigella sativa soft gel capsule for 8 weeks. Nigella sativa soft gel is a containing 1 gram of Nigella sativa oil and used twice a day. Control group: Patients in this group will receive avicel capsules for 8 weeks which are same size and shape, and used once a day.

Main outcome variables

serum level of ICAM and VCAM lipidemic and glycemic

indices oxidative parameters

General information

Reason for update

End of the sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20190506043494N1**

Registration date: **2019-11-08, 1398/08/17**

Registration timing: **prospective**

Last update: **2020-05-21, 1399/03/01**

Update count: **1**

Registration date

2019-11-08, 1398/08/17

Registrant information

Name

Omid Mohammad Tavakoli Rouzabehani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7581

Email address

omidmtr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-11-28, 1398/09/07

Actual recruitment end date

2020-02-29, 1398/12/10
Trial completion date
 2020-03-02, 1398/12/12

Scientific title
 The effects of nigella sativa extract oil supplementation on plasma level of ICAM-1, VCAM-1 , metabolic and oxidative parameters and nutritional status in patients with coronary artery disease

Public title
 Nigella sativa in coronary artery disease

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 age between 35-65 years BMI between 25 -45 Proof of 50% stenosis in at least one of the major coronary arteries in angiography Ability and willingness to collaborate on the project
Exclusion criteria:
 Any cardiovascular , kidney and chronic diseases consumption of herbal or nutritional supplements in the last 1-2 months heart failure function class 3 , 4 use of medicine or surgery for weight loss Use of cigarettes, alcohol and drugs pregnancy or lactation taking niacin and fibrates

Age
 From **35 years** old to **65 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **46**
 Actual sample size reached: **43**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The eligible participants will be randomly allocated to intervention and placebo groups using a software-generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In this double-blind study, no patient and investigator will be aware of the treatment assignments for the duration of the study. For blinding the trial, the Nigella sativa capsules and placebo, will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

City

tabriz

Province

East Azarbaijan

Postal code

5166/15731

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

IR.TBZMED.REC.1398.687

Health conditions studied

1

Description of health condition studied

coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

ICAM serum level

Timepoint

baseline and 8 week after intervention

Method of measurement

measurement via ELISA kit

2

Description

VCAM serum level

Timepoint

baseline and 8 week after intervention

Method of measurement

measurement via ELISA kit

3

Description

Lipid profile including HDL, LDL, TC and TG
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
HDL, TC and TG via enzymatic kit, LDL via friedewald equation

4

Description
Oxidative stress indices
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Measurement of serum levels of Total antioxidant capacity (TAC) and malondialdehyde (MDA) and Superoxide dismutase by spectrophotometry

5

Description
glycemic indices including FBS, HbA1C, insulin, HOMA-IR
Timepoint
before and after the 8 weeks supplementation
Method of measurement
Elisa and spectrometer

Secondary outcomes

1

Description
depression severity
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Beck Depression Inventory scale

2

Description
Physical activity level
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Via IPAQ questionnaire

3

Description
Quality of life
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Via MacNew questionnaire

Intervention groups

1

Description
Intervention group: Patients in this group will receive

Nigella sativa soft gel capsule for 8 weeks. Nigella sativa soft gel is a containing 1 gram of Nigella sativa oil and used twice a day.

Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive avicel capsules for 8 weeks which are same size and shape, and used once a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Medical Research Training Center
Full name of responsible person
Dr mohammad alizadeh
Street address
Daneshgah street, Shahid Madani Medical Research Training Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr juyban
Street address
Vice Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

omid mohammad tavakoli rouzbehani

Position

Msc student of clinical nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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