# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effects of Nigella sativa oil supplement on serum systemic inflammatory and oxidative stress markers and lipid profiles in dialysis patients: double-blind clinical trial

## Protocol summary

**Study aim**

Investigate the effects of Nigella sativa oil supplement on inflammatory serum systemic and oxidative stress markers and lipid profiles in hemodialysis patients.

**Design**

A clinical trial with a control group, with parallel groups, double-blind, phase 3 was performed on 50 hemodialysis patients.

**Settings and conduct**

Patients referred to the dialysis ward of Sabzevar Vasei Hospital with inclusion criteria were divided into two groups. All capsules ( Nigella sativa and placebo) had similar appearance.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: The study subjects were being dialyzed with polysulfone capillary dialyzers 3 times a week for 4 h per session The study, the hemodialysis procedure and type of dialyzer were not altered Must be able to swallow capsules Exclusion criteria: infectious diseases especially hepatitis, patients taking Nigella sativa oil, , patients taking omega-3 fatty acid supplements, L-carnitine, patients taking vitamin E and/or C supplements, patients taking steroidal and/or non-steroidal anti-inflammatory drugs

**Intervention groups**

Subjects in the intervention group received 2 capsules were prepared by Barij Essence Kashan Company (1000 mg Nigella sativa oil) daily for 8 weeks. whereas the placebo group received 2 placebo capsules containing medium-chain triglyceride oils were prepared by Barij Essence Kashan Company

**Main outcome variables**

inflammatory factors oxidative stress marke, lipid profiles

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180122038472N2**
Registration date: **2021-03-17, 1399/12/27**
Registration timing: **retrospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **0**

**Registration date**

2021-03-17, 1399/12/27

**Registrant information**

**Name**

roya akbarzadeh

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-04-04, 1396/01/15

**Expected recruitment end date**

2017-07-16, 1396/04/25

**Actual recruitment start date**

2017-04-04, 1396/01/15

**Actual recruitment end date**

2017-06-23, 1396/04/02

**Trial completion date**

2017-06-23, 1396/04/02

**Scientific title**
The effects of Nigella sativa oil supplement on serum systemic inflammatory and oxidative stress markers and lipid profiles in dialysis patients: double-blind clinical trial

**Public title**
The effect of black seed oil in dialysis patients

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
The study subjects were being dialyzed with polysulfone capillary dialyzers 3 times a week for 4 h per session The study, the hemodialysis procedure and type of dialyzer were not altered Must be able to swallow capsules

**Exclusion criteria:**
infectious diseases especially hepatitis patients taking Nigella sativa patients taking omega-3 fatty acid supplements, L-carnitine patients taking vitamin E and/or C supplements patients taking steroidal and/or non-steroidal anti-inflammatory drugs.

**Age**
From **45 years** old to **75 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **55**
More than 1 sample in each individual
Number of samples in each individual: **2**
At the begining and the end of week 8, 5 ml blood was collected from each patient after a 12 hour fast before hemodialysis
Actual sample size reached: **50**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
In the present study, participants and researchers during the study did not know whether each individual would be in the intervention or control group. For blinding, ginger and placebo capsules will be similar in appearance, packaging and labeling. For this double blind study, at the start of the study, a set of bottles containing capsule is encoded A and B, by a person other than the researcher so that the researcher is not aware of the type of capsules received by each group.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Sabzevar University of Medical Sciences

**Street address**
Sabzevar University of Medical sciences, Shohadaye Hastehei Blvd, Sabzevar, Iran

**City**
Sabzevar

**Province**
Razavi Khorasan

**Postal code**
9617913112

**Approval date**
2015-05-25, 1394/03/04

**Ethics committee reference number**
IR.MEDSSAB.REC.1394.12

## Health conditions studied

### 1

**Description of health condition studied**
chronic renal failure

**ICD-10 code**
I13.11

**ICD-10 code description**
end stage renal disease

## Primary outcomes

### 1

**Description**
inflammatory factors, oxidative stress marker, lipid profiles

**Timepoint**
At the begining and the end of week 8

**Method of measurement**
The serum hs-CRP concentration was determined using enzyme linked immune sorbent assay, the serum malondialdehyde (MDA) concentration was assessed using commercial colorimetric kits, the serum lipids was measured auto-analyzer with Pars Azmoon kits

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: 2 capsules containing 1000 mg of Nigella sativa oil made by Kashan Barij Essential Oil Company were given to the research units daily for 8 weeks.

**Category**

Placebo

**2**

**Description**

Control group: 2 capsules containing medium-chain triglyceride oils made by Kashan Barij Essential Oil Company were given to the research units daily for 8 weeks.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Vaseii hospital

**Full name of responsible person**

Ali Tajabadi

**Street address**

Vasei hospital, Shohadaye Hastehei Blvd, Sabzevar, Iran

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Fereshteh Ghorat

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drghorat@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Akram Kooshki

**Position**

associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

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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