Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of nigella sativa oil supplementation on kidney function tests, glycemic parameters, lipid profile, oxidative stress, inflammation, quality of life, and depression status in diabetic hemodialysis patients

Protocol summary

Study aim

determination of the Effect of Nigella Sativa oil supplementation on kidney function tests, glycemic parameters, oxidative stress, inflammation, quality of life and depression status in diabetic hemodialysis patients

Design

A clinical trial with control group, two groups of parallel, double-blind, Phase 3, on 46 hemodialysis patients, randomization using RAS software

Settings and conduct

This study will be conducted in the dialysis department of Imam Reza Hospital in Tabriz. The supplement and Placebo are produced in a completely similar way in terms of shape, color, and smell. supplements will be given to researchers and patients in a same and sealed cans. both patients and researchers are blind ton this Process.

Participants/Inclusion and exclusion criteria

Inclusion criteria : diabetic patients undergoing hemodialysis At least 6 months of hemodialysis his Maximum 10 years of hemodialysis history BMI between 18.5 to 30 inclusion criteria : Smoking and alcohol-abusing use of corticosteroids and NSAIDs Severe underlying diseases (stage 3 and 4 heart failure, acute liver and thyroid disease, malignancy)

Intervention groups

The intervention group will receive 2 capsules of 1000 mg of black seed oil (with lunch and dinner). the placebo group will take 2 capsules of 1000 mg of paraffin of cellulose for 12 weeks.

Main outcome variables

Laboratory tests including: renal function tests as creatinine, urea, uric acid, urine volume indices related to blood glucose including fasting blood sugar, HbA1c, glycosylated albumin (AlGl)

General information

Reason for update

In the first loading of content, a number of important and influential variables as a result of the study were mistakenly written in the secondary variables section; Therefore, in this form of correction, they were transferred to the primary variables. It was also forgotten that cholesterol and triglycerides were included in the variables, which were also included in the initial variables in their correction. Due to the fact that the nutritional status of patients could be a confounder, so the amount of energy and macronutrients consumed were included in our design as a secondary variable.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047027N1**
Registration date: **2020-05-31, 1399/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-06, 1400/09/15**
Update count: **1**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name
alireza rahmani
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 7736 4020
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a74.rahmani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-05-19, 1399/02/30
Expected recruitment end date
2020-08-20, 1399/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of nigella sativa oil supplementation on kidney function tests, glycemic parameters, lipid profile, oxidative stress, inflammation, quality of life, and depression status in diabetic hemodialysis patients

Public title
nigella sativa in hemodialysis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 18-60 BMI: 18.5-30 Diabetes At least 6 months of dialysis history maximum 10 years of dialysis history Ability and willingness to cooperate
Exclusion criteria:
Background diseases (heart failure stage 3 and 4, acute liver and thyroid disease, malignancy) nigella sativa oil consumption before entering the study Alcohol addiction, smoking receiving steroidal or nonsteroidal anti-inflammatory drugs sever reaction to supplement or placebo
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are randomly allocated to either a Nigella Sativa oil or control group by block randomization after stratification based on the frequency of hemodialysis per week (2 or 3 times per week) and the amount of blood sugar (blood glucose below 120, blood sugar between 120-200 and blood sugar above 200). This process is carried by a Statistics Specialist using RAS (Random allocation software) and in block sizes of 4. the sample size of each group is 23 people. A trained dietician will perform blinding, and the patients and researchers will be kept blinded to the allocation.
Blinding (investigator's opinion)
Double blinded
Blinding description
A total of 46 ESRD patients with ESRD selected by the inclusion criteria. after explaining the objectives of the study, and obtaining written consent, they will be entered into the study. Subjects are randomly divided into two groups of intervention and control. The supplements will be available to attendees every two weeks. Each patient should consume 2 capsules daily. The supplement and Placebo are produced in a completely similar way in terms of shape, color, and smell and in sealed cans.
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
attar ave
City
tabriz
Province
East Azarbaijan
Postal code
1653666741
Approval date
2020-05-04, 1399/02/15
Ethics committee reference number
IR.TBZMED.REC.1399.109

Health conditions studied

1

Description of health condition studied
Diabetic patients undergoing hemodialysis
ICD-10 code
E00–E90
ICD-10 code description
Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description
urea
Timepoint
Before baseline and after study
Method of measurement

Chemical method

2

Description
creatinine
Timepoint
Before baseline and after study
Method of measurement
jaffe method

3

Description
Glycated hemoglobin (HbA1c)
Timepoint
Before baseline and after study
Method of measurement
High-performance liquid chromatography (HPLC)

4

Description
glycated albumin (AlGl)
Timepoint
Before baseline and after study
Method of measurement
Enzymatic method

5

Description
Malondialdehyde (MDA)
Timepoint
Before baseline and after study
Method of measurement
Spectrophotometric method

6

Description
superoxide dismutase (SOD)
Timepoint
Before baseline and after study
Method of measurement
Spectrophotometric method

7

Description
total antioxidant capacity (TAC)
Timepoint
Before baseline and after study
Method of measurement
Spectrophotometric method

8

Description
High-sensitivity C-reactive protein (hs-CRP)
Timepoint
Before baseline and after study
Method of measurement
Turbidimetry

9

Description
Urine volume
Timepoint
Before baseline and after study
Method of measurement
Through the urine within 24 hours

10

Description
insulin
Timepoint
Before baseline and after study
Method of measurement
Eliza's method

11

Description
Hospital Anxiety and Depression Scale (HADS) questionnaire
Timepoint
Before baseline and after study
Method of measurement
Information on the questionnaire will be obtained from patients before and after treatment

12

Description
Kidney Disease Quality of Life (KDQOL) questionnaire
Timepoint
Before baseline and after study
Method of measurement
Information on the questionnaire will be obtained from patients before and after treatment

13

Description
uric acid
Timepoint
Before baseline and after study
Method of measurement
Spectrophotometric method

14

Description
High-density lipoprotein (HDL)
Timepoint
Before baseline and after study
Method of measurement
Spectrophotometric method

15

Description
Low-density lipoprotein (LDL)
Timepoint
Before baseline and after study
Method of measurement

Spectrophotometric method

Secondary outcomes

1

Description
Energy consumption
Timepoint
Before starting the study
Method of measurement
24-h Questionnaire

2

Description
Macronutrient consumption
Timepoint
Before starting the study
Method of measurement
24-h Questionnaire

Intervention groups

1

Description
Intervention group: The intervention group will receive 2 capsules of 1000 mg of black seed oil (with lunch and dinner) for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: the placebo group will take 2 capsules of 1000 mg of paraffin of cellulose for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
hemodialysis center of imam reza hospital
Full name of responsible person
ali tarighat esphanjani
Street address
attar neishbori
City
tabriz
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Postal code
1653666741
Phone
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Email
a74.rahmani@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
ali tarighat esphanjani
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Province
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1653666741
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a74.rahmani@gmail.com
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
ali tarighat esphanjani
Position
Associate Professor of Nutritional Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

ali tarighat esphanjani

Position

Associate Professor of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

alireza rahmani

Position

master of sience students

Latest degree

Bachelor

Other areas of specialty/work

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1653666741

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+98 21 7736 4020

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

My protocol will be shared

When the data will become available and for how long

beginning of 2021

To whom data/document is available

Dr Ali Trighat esphanjani

Under which criteria data/document could be used

Edit For analytical and epidemiological studies

From where data/document is obtainable

email : a74.rahmani@gmail.com

What processes are involved for a request to access data/document

sending an e-mail to : a74.rahmani@gmail.com

Comments