Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of Nigella sativa seed oil mixed with honey and placebo on the hepatic sonography and blood biochemical parameters of non-alcoholic fatty liver disease patients

Protocol summary

Study aim

Comparison of the effectiveness of Nigella sativa seed oil mixed with honey and placebo in the treatment of non-alcoholic fatty liver disease patients

Design

Randomized; block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of ten patients are used for the treatment assignments; double-blind; controlled with placebo; two group parallel design; single-center; phase 3 of clinical trial. Study population: patients with non-alcoholic fatty liver disease. Sample size: 120 patients.

Settings and conduct

The trial setting: Baqiyatallah Hospital. Protocol: sixty patients use 2.5 mL of Nigella sativa seed oil and 60 patients use 2.5 mL placebo orally every 12 hours for 3 months. Before intervention and 3 months after intervention the groups' liver sonography and blood levels of ALT, AST, LDL-C, HDL-C and triglyceride are compared with each other. Blinding: three different persons generate the random allocation sequence, enroll the participants and assign them to intervention groups. These persons, care providers, outcome assessors, data analyzer, investigators and participants are blinded to assignment to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients whose hepatic sonography shows they have fatty liver disease; age of 20 to 70 years. Exclusion criteria: Child-Pugh score above 7; hepatic disease other than non-alcoholic fatty liver disease; pregnant women; women planning pregnancy; lactating women.

Intervention groups

Sixty patients use 2.5 mL of Nigella sativa seed oil and 60 patients use 2.5 mL of placebo orally every 12 hours for 3 months.

Main outcome variables

Primary outcome variables: fatty liver grade, blood level of ALT, blood level of AST, blood level of LDL-C, blood level of triglyceride. Secondary outcome variable: blood level of HDL-C.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090804002288N13**
Registration date: **2018-06-06, 1397/03/16**
Registration timing: **retrospective**

Last update: **2018-06-06, 1397/03/16**
Update count: **0**

Registration date

2018-06-06, 1397/03/16

Registrant information

Name

Saeed Kianbakht

Name of organization / entity

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26147640109

Email address

kianbakht@imp.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date
2018-04-20, 1397/01/31
Actual recruitment start date
2017-04-04, 1396/01/15
Actual recruitment end date
2018-04-20, 1397/01/31
Trial completion date
empty

Scientific title
Comparison of the effects of Nigella sativa seed oil mixed with honey and placebo on the hepatic sonography and blood biochemical parameters of non-alcoholic fatty liver disease patients

Public title
Effect of Nigella sativa seed oil in treatment of non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients whose hepatic sonography shows they have fatty liver disease Age of 20 to 70 years
Exclusion criteria:
Child-Pugh score above 7 Hepatic disease other than non-alcoholic fatty liver disease Pregnant women Women planning pregnancy Lactating women
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of ten patients are used for the treatment assignments.
Blinding (investigator's opinion)
Double blinded
Blinding description
Three different persons generate the random allocation sequence, enroll the participants and assign them to intervention groups. These persons, care providers, outcome assessors, data analyzer, investigators and participants are blinded to assignment to the Nigella sativa seed oil and placebo groups.
Placebo
Used

Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Molla Sadra Street, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2015-11-01, 1394/08/10
Ethics committee reference number
IR.BMSU.REC.1394.149

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Fatty liver grade
Timepoint
Before intervention and 3 monthس after intervention
Method of measurement
Liver sonography

2

Description
Blood level of ALT
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Medical laboratory (kit)

3

Description
Blood level of AST
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Medical laboratory (kit)

4

Description
Blood level of LDL-C
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Medical laboratory (kit)

5

Description
Blood level of triglyceride
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Medical laboratory (kit)

Secondary outcomes

1

Description
Blood level of HDL-C
Timepoint
Before intervention and 3 month after intervention
Method of measurement
Medical laboratory (kit)

Intervention groups

1

Description
Intervention group: sixty patients use 2.5 mL of Nigella sativa seed oil orally every 12 hours for 3 months.
Category
Treatment - Drugs

2

Description
Control group: sixty patients use 2.5 mL of placebo orally every 12 hours for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Dr. Reza Mohtashami
Street address
Molla Sadra Street, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8805 0435
Email
reza_mohtashami1979@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Dr. Reza Hajiaghaee
Street address
ACECR Complex, Supa Boulevard, Poleh Kordan
City
Karaj
Province
Alborz
Postal code
3365166571
Phone
+98 26 3476 4010
Email
hajiaghaee@imp.ac.ir
Web page address
http://www.imp.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranian academic center for education culture and research
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
Iranian academic center for education culture and research

Full name of responsible person
Dr. Saeed Kianbakht

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

Street address
Institute of Medicinal Plants, ACECR Complex, Supa Boulevard, Poleh Kordan

City
Karaj

Province
Alborz

Postal code
3365166571

Phone
+98 26 3476 4010

Email
kianbakht@imp.ac.ir

Web page address
http://www.imp.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Dr. Saeed Kianbakht

Position
Assistant professor

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Email
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Web page address
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Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Dr. Saeed Kianbakht

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Assistant professor

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Email
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Web page address
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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
Yes - There is 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
All collected deidentified IPD are to be shared.

When the data will become available and for how long
Access period starting 6 months after publication for 1 year.

To whom data/document is available
Researchers working in university and scientific and industrial institutes.

Under which criteria data/document could be used
Only statistical analyses mentioned in the article resulting from the study for personal knowledge are permitted. Written request for access to data and documents and its aim must be certified by the highest ranking official of the work place of the requester.

From where data/document is obtainable

Dr. Saeed Kianbakht with the address ACECR Institute of Medicinal plants, P.O. Box: 31375-369, Iran.

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

Written request should be sent to the address Dr. Saeed Kianbakht, ACECR Institute of Medicinal Plants, P.O. Box: 31375-369, Iran. The documents or data file will be sent to the requester by email.

Comments