Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Aug 2026

Investigating the effect of royal jelly supplementation on blood lipids, liver enzymes, insulin resistance and inflammatory factors in patients with non-alcoholic fatty liver disease: a double-blind randomized clinical study

Protocol summary

Study aim

Determining the effect of royal jelly on blood lipids, liver enzymes, insulin resistance and inflammatory factors in patients with non-alcoholic fatty liver disease.

Design

This study is a randomized, double-blind, placebo-controlled trial for 8 weeks. The participants are randomly assigned to the royal jelly or placebo arm (23 people in each group) without knowing about the drug or placebo

Settings and conduct

In this study, 46 patients with non-alcoholic fatty liver referred to the nutrition clinic and the consultation and treatment center for liver and digestive system diseases of the hospital, who meet the inclusion criteria and do not meet the exclusion criteria, are included as samples. In this study, the sample are selected by easy sampling method. The table of random numbers is used to classify people into intervention and control groups

Participants/Inclusion and exclusion criteria

Patients with entry criteria of age 18 to 65 years and diagnosis of NAFLD and BMI between 25 and 40, exclusion criteria of history of liver disease, cardiovascular disease, lung disease, kidney disease, diabetes, celiac disease, thyroid disease

Intervention groups

In this study, patients in the intervention group received 3 capsules of 1000 mg daily for 8 weeks, and patients in the control group received a type of placebo supplement that looks exactly like Royal Gel capsules

Main outcome variables

LDL-C,HDL-C,ALT,AST ,GGT,TNF-a,CRP, QUICKI,HOMA-IR,TG,Cholestrol,Sex, age, height, weight, amount of physical activity,Waist circumference, hip circumference, ratio of waist circumference to hip circumference, serum glucose, serum insulin,Literacy level, financial status, total energy intake, carbohydrate intake, protein intake, total fat intake,Omega-3 fatty acids, intake of omega-6 fatty acids, intake of cholesterol, intake of fiber, intake of vitamin E, intake of vitamin C, intake of zinc, intake of Se

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110510006431N7**
Registration date: **2023-11-19, 1402/08/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-19, 1402/08/28**
Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Mahdi Shadnoush

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 1423

Email address

shadnoush@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of royal jelly supplementation on blood lipids, liver enzymes, insulin resistance and inflammatory factors in patients with non-alcoholic fatty liver disease: a double-blind randomized clinical study

Public title

Investigating the effect of royal jelly supplement in non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years diagnosis of NAFLD using ultrasound imaging Body mass index (BMI) 25 and above fasting blood sugar less than 126 no history of alcohol consumption or alcohol consumption less than 10 grams per day in women and less than 20 grams per day in men

Exclusion criteria:

Smoking history of liver, cardiovascular, pulmonary, kidney disease, celiac disease use of lipid-lowering drugs regular exercise six months before the study basic diet changes weight change of more than 5% in 3 months before screening History of gastric surgeries for weight loss patients using dietary supplements containing n-3 or n-6 fatty acids, vitamin D, E and other antioxidants or fiber supplements in the 12 weeks before the start of the study history of thyroid problems non-compliance Principles of the study protocol

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are divided into 2 intervention groups (as a group receiving royal jelly supplement) and a control group (as a group receiving placebo), in order to randomly assign patients to two groups, the stratified block randomization method is used to Randomization is performed by a block randomization program provided by an external randomization service based on age and gender. An investigator will screen and enroll participants, and the randomization sequence will be performed sequentially through identical sealed capsule containers assigned to participants at enrollment. The randomization code will be provided in sealed envelopes only to be broken at the end of the clinical trial (before statistical analysis) or in the event of serious adverse events

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants are randomly assigned to the royal jelly or placebo arm (23 people in each group) using a random number table, so that they are not aware of the drug or placebo use. In this study, patients in the intervention group received 3 capsules of 1000 mg daily for 8 weeks, and patients in the control group received a type of placebo supplement that looks exactly like Royal Gel capsules. Due to the double-blindness of the study, the researcher who was taking and recording the data of the samples was also blind to the drug or placebo in the samples, and only the statistician would be aware of their placement in each of the two mentioned groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Farhikhtegan Hospital-Islamic Azad university

Street address

Tehran, the end of Shahid Sattari North Highway, University Square, towards Hesarek, Farhikhtegan Hospital

City

Tehran

Province

Tehran

Postal code

1477899679

Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.IAU.FARHIKHTEGANH.REC.1402.006

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
TG،Total Cholestrol ، LDL ، HDL C ،ALT، AST ،GGT ، TNF a ، CRP
Timepoint
At the beginning of the study and 8 weeks after the intervention
Method of measurement
5 cc of blood is taken to measure the concentration of liver enzymes, lipid profile, inflammatory factors and it is measured by enzymatic methods and using a kit

Secondary outcomes

1

Description
Weight, body mass index (BMI), waist circumference, hip circumference, ratio of waist circumference to hip circumference, serum glucose, serum insulin, insulin resistance (HOMA-IR), quantitative insulin sensitivity index (QUICKI)
Timepoint
At the beginning of the study and after 8 weeks after the intervention
Method of measurement
Taking blood samples using laboratory methods, the weight of each patient is measured with a scale with an accuracy of 100 grams, and the height of each patient without shoes is measured with a height meter with an accuracy of 0.5 cm. The body mass index (BMI) of the patients is calculated, the patient's waist and hips are measured using a tape measure with an accuracy of 0.5 cm, and finally, the body fat percentage of the patients is measured with an in-body device

Intervention groups

1

Description
This study is a randomized, double-blind, placebo-controlled trial for 8 weeks. The participants are randomly assigned to the royal jelly or placebo arm (23 people in each group) without knowing about the drug or placebo. In this study, the patients of the intervention group received 3 capsules of 1000 mg daily with the active ingredient 10-hydroxy-2-desenoic acid for 8 weeks, and the patients of the control group received a type of placebo supplement that looks exactly like the royal gel capsule. This supplement and placebos will be prepared and supplied by Koze Asal Company. Due to the double-blindness of the study, the researcher who was taking and recording the data of the samples was also blind to the drug or placebo in the samples, and only the statistician would be aware of their placement in each of the two mentioned groups.Randomization is done by a block randomization program provided by an external randomization service. An investigator will screen and enroll participants, and the randomization sequence will be performed sequentially through identical sealed capsule containers assigned to participants at enrollment. The randomization code will be provided in sealed envelopes only to be broken at the end of the clinical trial (before statistical analysis) or in the event of serious adverse events
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان فرهیختگان
Full name of responsible person
فاطمه حسن نیا
Street address
jahanara
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Email
hasannia.fatemeh76@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahdi Shadnoush
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Shahid Hafezi
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Tehran
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1981619573
Phone
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Email
info@nnftri.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Hospital
Proportion provided by this source
20
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
fateme hasannia
Position
student
Latest degree
Bachelor
Other areas of specialty/work
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Email
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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
fateme Hasannia
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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hasannia.fatemeh76@gmail.com

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