

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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 Cholesterol, 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1436674534

##### Phone

+98 21 8804 2491

##### 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 Shadnough

##### Street address

Shahid Hafezi

##### City

Tehran

##### Province

Tehran

##### Postal code

1981619573

##### Phone

+98 21 2235 7483

##### 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**

Nutrition

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

fateme Hasannia

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

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**City**

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**Province**

Tehran

**Postal code**

1436674534

**Phone**

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**Email**

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