Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 2026

The effect of rosa canina supplement on liver enzymes, lipid profile, fasting blood glucose and anthropometric indices in patients with non-alcoholic fatty liver disease under weight loss diet

Protocol summary

Study aim

Determining the effect of wild rosa canina supplement on liver enzymes, lipid pattern, fasting blood glucose and anthropometric indices in non-alcoholic fatty liver patients under weight loss diet.

Design

Clinical trial with a control group; parallel groups; bilaterally blind; randomization with RAS software; on 100 patients

Settings and conduct

The current study is a clinical trial designed to investigate the effect of wild nester supplement on liver enzyme levels, lipid pattern, fasting blood glucose and body composition in NAFLD patients under a weight loss diet. People who meet the criteria for entering the study and are confirmed by an internal physician with ultrasound after obtaining a written consent will be included in the study by referring to the Shafa specialized clinic in Khalkhal city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with non-alcoholic fatty liver disease Exclusion criteria: pregnant mothers

Intervention groups

The intervention group will be given a weight loss diet and 1 gram of rosa canina twice a day in the form of a 500 mg capsule with a glass of water in the morning and evening snacks for 8 weeks. The control group will be given a weight loss diet and 1 gram of placebo twice a day in the form of a 500 mg capsule with a glass of water in the morning and evening meals for 8 weeks; It should be noted that this placebo will look exactly the same as the rosa canina capsule.

Main outcome variables

liver enzymes; lipid profile; anthropometric indicators; fasting blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059334N1**
Registration date: **2023-10-16, 1402/07/24**
Registration timing: **prospective**

Last update: **2023-10-16, 1402/07/24**
Update count: **0**

Registration date

2023-10-16, 1402/07/24

Registrant information

Name

Vahideh Aghamohammadi khiavi

Name of organization / entity

Khalkhal university of medical science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of rosa canina supplement on liver enzymes, lipid profile, fasting blood glucose and anthropometric indices in patients with non-alcoholic fatty liver disease under weight loss diet

Public title
Effect of rosa canina on non alcoholic fatty liver disaese
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All people with non-alcoholic fatty liver disease referring to Internist
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling by randomization method with RAS software and allocation of 3-digit codes with sealed envelopes will be done by a person outside the study, then people will be allocated to two groups by block randomization based on age.
Blinding (investigator's opinion)
Double blinded
Blinding description
The principal investigator of this study and the study participants are kept blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Khalkhal university of medical science
Street address
Khalkhal university of medical science, Mozaffar Azizi st , imam blv
City
Khalkhal
Province
Ardabil
Postal code
۵۶۸۱۷۶۱۳۵۱
Approval date
2023-08-05, 1402/05/14
Ethics committee reference number
IR.KHALUMS.REC.1402.007

Health conditions studied

1

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

Primary outcomes

1

Description
Liver enzymes
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement
Method of measurement
Pars azmoon liver enzymes kit

2

Description
Lipid profile
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement
Method of measurement
Pars Azmoun Cholesterol Quantification Kit

3

Description
fasting blood sugar
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement
Method of measurement
Glucose Quantification Kit Pars Azman

4

Description
Body weight
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement

Method of measurement
Seca scale

Secondary outcomes

1

Description
Blood pressure
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement
Method of measurement
Barometer

2

Description
Waist circulate
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement
Method of measurement
Measuring tape

3

Description
Body fat mass
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement
Method of measurement
Inbody body analyzer

4

Description
Body muscle mass
Timepoint
At the beginning of the study and 8 weeks after the start of taking rosa canina supplement
Method of measurement
Inbody body analyzer

Intervention groups

1

Description
Intervention group: The intervention group will be given a weight loss diet and 1 gram of rosa canina 2 times a day in the form of 500 mg capsules with a glass of water in the morning and evening snacks for 8 weeks. It was disinfected and packaged in Ardabil University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: The control group will be given a weight loss diet and 1 gram of placebo twice a day in the form of a 500 mg capsule with a glass of water in the morning and evening meals for 8 weeks; It should be noted that this placebo will look exactly the same as the rosa canina capsule. Starch powder will be used for placebo capsules. Placebo capsules will be prepared by the Faculty of Pharmacy of Ardabil University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa clinic
Full name of responsible person
Vahideh Aghamohammadi Khiavi
Street address
Shafa clinic, Mozaffar Azizi st, Imam blv
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v.aghamohammadi@khalums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khalkhal university of medical science
Full name of responsible person
hamed rezakhani moghadam
Street address
khalkhal university of medical science , Mozaffar azizi st , Imam blv
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Phone
+98 45 3242 6801
Email
h.rezakhani@khalums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Khalkhal university of medical science

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

Khalkhal university of medical science

Full name of responsible person

Vahideh Aghamohammadi khiavi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Khalkhal university of medical science

Full name of responsible person

Vahideh Aghamohammadi khiavi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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Fax

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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

Not applicable

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