Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Capsule production containing Phytosomes carrying standardized Rosa canina L seed extract based on tiliroside separately and in combination with curcumin and catechins in patients with Non-Alcoholic Liver Disease (NAFLD)

Protocol summary

Study aim
Investigating the effect of edible phytosome containing Rosa Canina L. extract on fatty liver grade change

Design
A randomized clinical trial, triple blind, 144 patients enrolled and followed for 8 weeks

Settings and conduct
Patients diagnosed with fatty liver are randomly divided into oral capsule and placebo groups, patients are evaluated for 8 weeks and fibroscan is recorded in patients at baseline and at the end of 8 weeks. Patients will be evaluated in the gastroenterology and liver specialist office.

Participants/Inclusion and exclusion criteria
Patients with sonographic findings of grade 1 to 3 fatty liver (or if possible based on fibroscan results), not pregnant, not breastfeeding, not taking lipid-lowering drugs, thyroid and hormonal drugs, alcohol, hepatotoxic drugs The criteria for not entering the study include: any findings related to cirrhosis, hepatitis, pregnancy, breastfeeding, fatty liver due to secondary reasons such as alcohol consumption, use of blood sugar and lipid lowering drugs, anti-inflammatory and any drug affecting the liver, people with diseases renal, respiratory, thyroid diseases, having a history of weight loss (more than 5% in the last 6 months) or bariatric surgery, participating in other studies related to clinical trials

Intervention groups
Intervention group: receive the first dose (62) of phytosome formulation containing Rosa canina L. extract in addition to conventional treatment Intervention group: receive the second dose (125) of phytosome formulation containing Rosa canina L extract in addition to conventional treatment Intervention group: receive the third dose (250) of phytosome formulation containing Rosa canina L extract in addition to conventional treatment Control group: receive placebo in addition to conventional treatment

Main outcome variables
Changing the grade of fatty liver based on fibroscan results

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100420003760N8**
Registration date: **2024-01-23, 1402/11/03**
Registration timing: **prospective**

Last update: **2024-01-23, 1402/11/03**
Update count: **0**

Registration date
2024-01-23, 1402/11/03

Registrant information

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Marzieh Rashidipour
Name of organization / entity
Lorestan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Capsule production containing Phytosomes carrying standardized Rosa canina L seed extract based on tiliroside separately and in combination with curcumin and catechins in patients with Non-Alcoholic Liver Disease (NAFLD)

Public title

Investigating the effect of mountain Rosa canina L in the treatment of fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with sonographic findings of grade 1 to 3 fatty liver (or if possible based on fibroscan results)

Exclusion criteria:

Pregnant and lactating women Any finding of cirrhosis Hepatitis Pregnant and lactating women Fatty liver due to secondary causes such as alcohol consumption Taking hypoglycemic drugs Taking lipid-lowering drugs Taking anti-inflammatory drugs and any drugs affecting the liver People with kidney, respiratory, thyroid diseases Having a history of weight loss (more than 5% in the last 6 months) or bariatric surgery Participation in other studies related to clinical trials

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients into four groups and also using stratified random allocation. In this way, classes are made based on age group (below 40 years and older or equal to 40 years), gender (male and female) and severity (mild, moderate or severe). Within each class, random permutation blocks are used to assign samples to the required groups. To create random sequences, letters A, B , C or D(corresponding to the experimental group) will be used as follows. ABCD: 0-3 ABDC: 4-7 ACBD: 8-11 ACDB:12-15 . . DABC DBAC DCAB DCBA: 92-95 Then a corner of the table of random numbers is selected and two-digit numbers are read from top to bottom, and finally, according to the read number, a random sequence of letters A to D is registered in the desired floor. Finally, a random sequence of letters A to D (corresponding to the 4 experimental groups) will be created in each class of all existing classes, and the samples will be assigned to 4 groups based on this random sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

A random sequence of letters A to D (corresponding to 4 experimental groups) will be created in each class from all the existing classes, and the samples will be assigned to 4 groups based on this random sequence. This study will be triple blind, which means that the pain intensity disease severity assessor, the patient and the data analyst are not aware of the type of treatment assigned to the patient. In addition, the decipherer is not a member of the research team, and the capsules in all groups are completely identical in appearance. Data registration in the statistical software and data analysis is done by the statistical consultant without mentioning the names of the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Lorestan University of Medical Sciences

Street address

No 20, Anooshirvan Rezaei Square, Lorestan University of Medical Sciences

City

khorramabad

Province

Lorestan

Postal code

6816889468

Approval date

2023-10-10, 1402/07/18

Ethics committee reference number

IR.LUMS.REC.1402.204

Health conditions studied

1

Description of health condition studied

Non-Alcoholic 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, and after intervention. Fibroscan time 0 and 360

Method of measurement

Through Questionnaire and Fibroscan.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive the first dose (62 mg phytosome) of phytosome formulation containing Rosa Canina L. in addition to conventional treatment. The capsule will be taken orally for 8 weeks, on a 500 mg capsule that contains the compounds tiliroside, catechin and curcumin. The capsules are prepared by Kimia Daru Company.

Category

Treatment - Drugs

2

Description

Intervention group: receive the first dose (125 mg phytosome) of phytosome formulation containing Rosa Canina L. in addition to conventional treatment. The capsule will be taken orally for 8 weeks, on a 500 mg capsule that contains the compounds tiliroside, catechin and curcumin. The capsules are prepared by Kimia Daru Company.

Category

Treatment - Drugs

3

Description

Intervention group: receive the first dose (250 mg phytosome) of phytosome formulation containing Rosa Canina L. in addition to conventional treatment. The capsule will be taken orally for 8 weeks, on a 500 mg capsule that contains the compounds tiliroside, catechin and curcumin. The capsules are prepared by Kimia Daru Company.

Category

Treatment - Drugs

4

Description

Control group: receive placebo (0 mg phytosome) in addition to conventional treatment. The capsule will be taken orally for 8 weeks, on a 500 mg capsule that contains the compounds catechin and curcumin. The capsules are prepared by Kimia Daru Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and liver specialist office

Full name of responsible person

Marzieh Rashidipour

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No. 140, Razi Ave. Pajohandeh Blvd, Herbal Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Bahram Rasoulian

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Grant name

Khoram-Abad University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Marzieh Rashidipour
Position
Assistant Professor
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data, such as information about the main consequence or similar, can be shared
When the data will become available and for how long
Start the access period 18 months after printing the results.
To whom data/document is available
Data will only be available to researchers working at

academic and scientific institutions

Under which criteria data/document could be used

The data will only be used to inform the results of the study

From where data/document is obtainable

Lorestan University of Medical Sciences

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

Refer to Lorestan University of Medical Sciences, Vice Chancellor of Research and Technology, Research Projects Department, Management of Research Projects Department, 066333120175, Mrs. Sajedi , fax:066333120173 call mrs. zarei 0989167083314

Comments