Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

The effect of herbal product from Berberis integerrima on ultrasound image echogenicity of patients with Non-Alcoholic Fatty Liver Disease

Protocol summary

Study aim

The effect of herbal product from Berberis integerrima on ultrasound image echogenicity of patients with Non-Alcoholic Fatty Liver Disease

Design

Two arm parallel group randomized trial double blinded clinical trial (III), 60 patients The method of randomization in this study is quadruple blocking method and the randomization unit is individual and tool is statistical software

Settings and conduct

After reviewing the inclusion and exclusion criteria and receiving informed consent for participating, the patients Will be divided to two group are provided and asked to consume 2 spoon syrup daily after breakfast and dinner for three months and then ultrasound and lab tests will be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 20 to 60 years with increased hepatic echogenicity (grade 2 non-alcoholic fatty liver) based on ultrasonographic findings Exclusion criteria: Type 2 DM; cardiovascular disease, liver disease; other serious diseases such as cancer; kidney failure and celiac disease, etc .; pregnancy; lactation, taking drugs that cause and stimulate liver steatosis; taking any type of lipid-lowering drugs and fibrates; existence of malnutrition; adherence to special diets such as vegetarianism and raw eating; Alcohol, cigarettes and drugs, acute or underlying psychiatric disorders Drop out criteria: Tendency to leave the plan, do not take medication for a week, drug allergy, occurrence of pregnancy, Non-compliance with dietary instructions more than 30%.

Intervention groups

The control group: placebo syrup contained simple syrup with 2.5% of the studied extract Intervention group: Barberry-based herbal syrup (75mg/ml), 2 spoon (10ml) per day

Main outcome variables

Treatment protocol, degree of fatty liver, AST, ALT, age, sex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210524051376N1**
Registration date: **2021-06-30, 1400/04/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-30, 1400/04/09**
Update count: **0**

Registration date

2021-06-30, 1400/04/09

Registrant information

Name

Narjes Gorji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9592

Email address

n.gorji@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of herbal product from Berberis integerrima on ultrasound image echogenicity of patients with Non-Alcoholic Fatty Liver Disease

Public title
The effect of herbal product from Berberis integerrima on Non-Alcoholic Fatty Liver Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Increased liver echogenicity (grade 2 non-alcoholic fatty liver) based on ultrasonographic findings

Exclusion criteria:
The underlying illness (Diabetes mellitus, cardiovascular diseases, liver disease (cirrhosis, alcoholic liver disease, viral hepatitis, autoimmune hepatitis, primary biliary cirrhosis, biliary obstruction, hepatic damage induced by hereditary hemochromatosis drugs, sclerosis cholangitis and α deficiency of an antitrypsin), other serious diseases such as cancer; kidney failure and celiac disease Pregnancy Lactation Drug history with increase hepatic steatosis risk (Tamoxifen, valproate sodium, ... Antihyperlipidemic drugs Malnutrition special diets such as vegetarianism and raw eating Alcohol consumption Smoking and addiction Acute psychiatric disorder

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is done as an easy sampling and allocation of the drug with a quadruple block randomization pattern Two types of herbal and classical medicines were prepared by the researcher in identical shapes, sizes and colors, and then they were mediated by a person who had nothing to do with this research. Encoded in closed-form packages and enclosed to research samples based on the list of random numbers created by the person above. The code list is kept secret and kept until the data analysis, the end of the study day, is kept confidential. Randomized study codes are opened when statistical tests are performed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Two types of herbal and classical medicines were prepared by the researcher in identical shapes, sizes and colors, and then to hide the allocation and to ensure that they did not know what type of drug they used, they were mediated by a person who had nothing to do with this research. Encoded in closed-form packages and enclosed to research samples based on the list of random numbers created by the person above. The code list is kept secret and kept until the data analysis, the end of the study day, is kept confidential. Randomized study codes are opened when statistical tests are performed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol university of medical science

Street address
Ganjafrooz st. Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
47176-47745

Approval date
2019-08-18, 1398/05/27

Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.158

Health conditions studied

1

Description of health condition studied
Fatty liver

ICD-10 code
K76.0

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

Primary outcomes

1

Description
The ultrasound image echogenicity of patients with Non-Alcoholic Fatty Liver Disease

Timepoint
3 months after the start of the intervention

Method of measurement
Ultrasonography grading and lab test (TG, LDL,HDL, AST ,ALT)

Secondary outcomes

1

Description
Body wheight
Timepoint
3 months after the start of the intervention
Method of measurement
Measure weight (kg)

Intervention groups

1

Description
Intervention group: herbal syrup from Berberis integerrima (75mg /mL) 2 cups (10ml) per day for three months after breakfast and dinner and return to the same centers for ultrasound and testing. Diets with the aim of reducing daily fat intake and eliminating unhealthy fast foods and carbonated beverages are given to both groups in exactly the same way based on available clinical guidelines. Patients are monitored monthly and their changes in weight (BMI) and blood pressure are recorded, and they are also asked to submit their diet three consecutive days each month.
Category
Treatment - Drugs

2

Description
Control group: Placebo contains simple syrup with 2.5% of the studied extract 2 cups (10ml) a day for three months after breakfast and dinner and go to the same centers again for ultrasound and testing. Diets with the aim of reducing daily fat intake and eliminating unhealthy fast foods and carbonated beverages are given to both groups in exactly the same way based on available clinical guidelines. Patients are monitored monthly and their changes in weight (BMI) and blood pressure are recorded, and they are also asked to submit their diet three consecutive days each month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Traditional medicine health center,Babol
Full name of responsible person
Narjes Gorji
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Reza Ghadimi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Narjes Gorji
Position
Assistant professor
Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

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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
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