

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

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

#### Protocol summary

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

#### 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

#### 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  $\alpha$  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 weight

#### 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

##### Street address

Shahid Sargord Ghasemi

#### City

Babol

#### Province

Mazandaran

#### Postal code

47176-47745

#### Phone

+98 11 3219 4730

#### Email

n.gorji@mubabol.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr Reza Ghadimi

##### Street address

Ganjafrooz St.

##### City

Babol

##### Province

Mazandaran

##### Postal code

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##### Phone

+98 11 3219 9592

##### Email

rezaghadimi@yahoo.com

#### 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

**Street address**

Ganjafrooz st.

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**Email**

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**Person responsible for scientific 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**

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

Babol University of Medical Sciences

**Full name of responsible person**

Narjes Gorji

**Position**

Assistant professor

**Latest degree**

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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