

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of berberis integerrima extract on liver enzymes, liver steatosis and fibrosis in patients with non-alcoholic fatty liver disease (NAFLD) following the DASH diet: a double-blind randomized clinical trial.

Protocol summary

Study aim

Investigating the effect of berberis integrimma extract on disease severity and inflammatory indices in patients with ulcerative colitis

Design

Parallel-groups, double-blind, randomized clinical controlled trial

Settings and conduct

60 patients with non-alcoholic fatty liver disease will be randomly assigned to intervention and control groups. In the intervention group, participants will receive 2 tablespoons of berberis integerimna extract daily. In the placebo group, participants consume the same amount of placebo. The study period will be 12 weeks. The DASH diet will be prescribed for both groups according to the characteristics of the participants. Also, to control participants in terms of taking supplements and placebo and prevent the samples from falling, the follow-up of patients would occur every two weeks by phone.

Participants/Inclusion and exclusion criteria

Entry criteria: age 18 years and older; diagnosis of the disease by ultrasound; ALT >30 IU/L in men and ALT >19 IU/L in women; BMI greater than 18.5 and less than 30. Non-entry criteria: pregnancy or breastfeeding; alcohol consumption; history of diseases including liver cirrhosis; viral hepatitis; cardiovascular diseases; cancer; relapse and hospitalization of the patient; allergy to barberry.

Intervention groups

In the intervention group, participants receive 2 tablespoons of berberis integerimna extract daily. In the placebo group, participants consume the same amount of placebo. The study period will be 12 weeks.

Main outcome variables

changes in the severity of liver steatosis; changes in the severity of liver fibrosis; Serum levels of liver enzymes (ALT, AST, ALP, GGT)

General information

Reason for update

1. Cooperation and sponsorship of Sanabel Daru Company to prepare the extract 2. Using berberis integerrima syrup instead of berberis integerrima capsules

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051098N6**
Registration date: **2024-02-03, 1402/11/14**
Registration timing: **prospective**

Last update: **2024-11-10, 1403/08/20**

Update count: **1**

Registration date

2024-02-03, 1402/11/14

Registrant information

Name

Sayyed Saeid Khayyatadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

khayyatadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of berberis integerrima extract on liver enzymes, liver steatosis and fibrosis in patients with non-alcoholic fatty liver disease (NAFLD) following the DASH diet: a double-blind randomized clinical trial.

Public title

The effects of berberis integerrima extract on the non-alcoholic fatty liver disease (NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 and older Diagnosis of the disease by ultrasound with a standard method ALT >30 IU/L in men and ALT >19 IU/L in women BMI higher than 18.5 and less than 30

Exclusion criteria:

Taking corticosteroids Pregnancy and breastfeeding Alcohol consumption (men: ethanol > 140 g per week, women: ethanol > 70 g per week) History of diseases including liver cirrhosis, viral hepatitis, cardiovascular diseases, cancer Medication history including corticosteroids, non-steroidal anti-inflammatory drugs, drugs affecting blood sugar, lipid profile, body weight and liver function. Disease relapse and patient hospitalization Barberry allergy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation between two groups will perform using Random allocation version 2 software. The random sequence will generate with this software using a simple random allocation method, and each number will allocate to an intervention group A or B. Allocation concealment will perform by calling or sending message to a third-person who is unaware of intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators and data collectors will be blinded to the study groups. Allocation concealment will

perform by calling or sending message to a third-person who is unaware of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

School of public health, Shahid Sadoughi University of Medical Sciences, Shohadaye Gornam Blvd., Alam Square, Yazd

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Province

Yazd

Postal code

8915173160

Approval date

2023-11-20, 1402/08/29

Ethics committee reference number

IR.SSU.SPH.REC.1402.105

Health conditions studied**1****Description of health condition studied**

Non-alcoholic fatty liver disease (NAFLD)

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes**1****Description**

Serum levels of alanine transaminase enzyme

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Enzymatic method

Secondary outcomes

1

Description

Severity of hepatic steatosis

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Fibroscan analysis

2

Description

Severity of liver fibrosis

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Fibroscan analysis

3

Description

Severity of liver stiffness

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Fibroscan analysis

4

Description

Controlled Attenuation Parameter (CAP)

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Fibroscan analysis

5

Description

Serum levels of aspartate aminotransferase

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Enzymatic method

6

Description

Serum levels of alkaline phosphatase

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Enzymatic method

7

Description

Serum levels of gammaglutamyltransferase

Timepoint

Before intervention- after intervention (12 weeks after receiving barberry extract or placebo)

Method of measurement

Enzymatic method

Intervention groups

1

Description

Intervention group: In the intervention group, participants will receive 2 tablespoons of barberry extract (Prepared by Sanabel Daru Company) for 12 weeks. The DASH diet will be prescribed for both groups according to their characteristics and individual requirements.

Category

Treatment - Other

2

Description

Control group: In the placebo group, participants will receive a placebo syrup with a similar appearance to the intervention syrup, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mohammad Hossein Ahrarizdi's clinic

Full name of responsible person

sayed saeid khayyatzadeh

Street address

Maryam Medical building, Maryam Alley, Kashani St., Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi abargouei

Street address

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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

Yazd University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Sanabel Daroo Company

Full name of responsible person

Dr Mohsen Naseri

Street address

Unit 1, No. 78, West Nusrat St., Tohid Square, Tehran

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1457785693

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Email

info@sanabel.ir

Web page address

<https://sanabel.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanabel Daroo Company

Proportion provided by this source

50

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Sayyed Saeid Khayatzadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Full name of responsible person

Sayyed Saeid Khayatzadeh

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Position

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available