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 Khayyatzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 9100

Email address
khayyatzadeh@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 Gomnam Blvd., Alam Square, Yazd
City
Yazd
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
sayyed 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

Central Administration, Bahonar Sq., Yazd

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8916978477

Phone
+98 35 3628 8114

Email
dvc.research@ssu.ac.ir

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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Tehran

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Tehran

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1457785693

Phone
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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 Khayyatzadeh

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Position
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Latest degree
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Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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