Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of hydroalcoholic extract of Berberis fruits integerrima on the lipid profile, antioxidantparameters and liver and kidney function tests in patients with nonalcoholic fatty liver disease

Protocol summary

Study aim

Evaluation of the Barberry fruits effects on patient with Non-alcoholic fatty liver disease

Design

The present randomized double-blind clinical trial study was conducted on nonalcoholic fatty liver patients who referred to Ali-Ebn-Abitaleb Rafsanjan University Hospital and their disease were confirmed with the increased liver enzymes and ultrasound of the liver tissue by an expert physician. 42 patients separated to two groups, randomly using table of random number: control group and case group

Settings and conduct

The present double-blind clinical trial was performed on NAFLD patients who referred to Ali-Ebn-Abitaleb Rafsanjan Hospital. Control group received cellulose, case group received hydro-alcoholic extract of Berberis. Patients, care provider and data analyzer were blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from nonalcoholic fatty liver; elevated levels of AST, ALT; the age range of 20-45 years and the signing a declaration of consent. Patients using alcohol, daily berberis and having allergy to berberis and its compounds; patients with diabetes; high blood pressure; perceptual disorders; nephrotic syndrome; ischemic heart diseases; chronic liver disease such as hepatitis, and pregnancy and lactation were excluded from the study.

Intervention groups

Control group received a gelatin capsule contain 750 mg cellulose; case group received a gelatin capsule contain 750 mg hydro-alcoholic extract of Berberis integerrima every 12 hours for two months.

Main outcome variables

Biochemical factors; functional liver and renal test; antioxidant parameter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044196N1**
Registration date: **2019-07-31, 1398/05/09**
Registration timing: **retrospective**

Last update: **2019-07-31, 1398/05/09**
Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Mehdi Afshari nasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 5900

Email address

mehdi.af.1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-17, 1396/07/25

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

2017-10-17, 1396/07/25

Actual recruitment end date

2018-12-11, 1397/09/20

Trial completion date

2019-01-15, 1397/10/25

Scientific title
The effect of hydroalcoholic extract of Berberis fruits integerrima on the lipid profile, antioxidantparameters and liver and kidney function tests in patients with nonalcoholic fatty liver disease

Public title
The effect of hydroalcoholic extract of Berberis fruits integerrima on the lipid profile, antioxidantparameters and liver and kidney function tests in patients with nonalcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from nonalcoholic fatty liver Elevated levels of Aspartate aminotransferase (AST) Alanine aminotransferase (ALT) Age range of 20-45 years old Signing a declaration of consent

Exclusion criteria:
Using alcohol Using daily berberis Having allergy to berberis and its compounds, Patients with diabetes High blood pressure Patient with perceptual disorders Nephrotic syndrome Ischemic heart diseases Patient with chronic liver disease such as hepatitis Pregnancy or lactation

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **42**
Actual sample size reached: **41**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients separated to two groups, randomly using table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant (patients), care provider and data analyser have no information about the type of treatment substance

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Council of Rafsanjan University of Medical Sciences

Street address
Rafsanjan University of Medical Sciences, Department of Biochemistry

City
Rafsanjan

Province
Kerman

Postal code
7718134567

Approval date
2017-10-17, 1396/07/25

Ethics committee reference number
IR.RUMS.REC.1396.110

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver

ICD-10 code
K76.0

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

Primary outcomes

1

Description
Fasting blood glucose

Timepoint
Before and after treatment

Method of measurement
measured using Pars azmun kit

2

Description
total cholesterol

Timepoint
Before and after treatment

Method of measurement
measured using Pars azmun kit

3

Description
triglyceride

Timepoint
Before and after treatment

Method of measurement
measured using Pars azmun kit

4

Description
LDL-C
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

5

Description
HDL-C
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

6

Description
Alanine aminotransferase
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

7

Description
Aspartate aminotransferase
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

8

Description
Alkaline phosphatase
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

9

Description
total bilirubin
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

10

Description
and direct bilirubin
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

11

Description
urea
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

12

Description
creatinine
Timepoint
Before and after treatment
Method of measurement
measured using Pars azmun kit

13

Description
glutathione peroxidase enzyme
Timepoint
Before and after treatment
Method of measurement
ZellBio kit

14

Description
malondialdehyde
Timepoint
Before and after treatment
Method of measurement
ZellBio kit

15

Description
total antioxidant
Timepoint
Before and after treatment
Method of measurement
ZellBio kit

16

Description
blood pressure
Timepoint
Before and after treatment
Method of measurement
Blood pressure monitor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: received a gelatin capsule contain

750 mg hydro-alcoholic extract of Berberis integerrima . Berberis fruits were taken from mountainous areas of Bardsir, Kerman, Southeast of Iran and confirmed by Iranian institute of research & development in chemical industries and they were extracted in that institute.

Category

Treatment - Other

2

Description

Control group: received a gelatin capsule contain 750 mg cellulose every 12 hours

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Ebn-Abitaleb Rafsanjan University Hospital

Full name of responsible person

Mehdi Afshari

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Rafsanjan University of medical science, Department of Biochemistry

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Zare

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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Mehdi Afshari

Position

Ms.c student

Latest degree

Master

Other areas of specialty/work

Biochemistry

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Person responsible for updating data

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Latest degree
Bachelor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
No - There is not 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