

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of hydroalcoholic extract of Berberis fruits integerrima on the lipid profile, antioxidant parameters 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, antioxidant parameters 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, antioxidant parameters 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

Street address

Rafsanjan University of medical science, Department of Biochemistry

City

Rafsanjan

Province

Kerman

Postal code

7718134567

Phone

+98 34 3131 5175

Email

mehdi.af.1372@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Zare

Street address

Rafsanjan University of medical science, Department of biochemistry

City

Rafsanjan

Province

Kerman

Postal code

7718134567

Phone

+98 34 3131 5175

Email

mehdi.af.1372@gmail.com

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

Street address

Department of Biochemistry, Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7718134567

Phone

+98 34 3131 5175

Email

mehdi.af.1372@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Mehdi Afsahri

Position

MS.c student

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

Department of Biochemistry, Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7718134567

Phone

+98 34 3131 5175

Email

mehdi.af.1372@gmail.com

Postal code

7718134567

Phone

+98 34 3428 5900

Fax**Email**

mehdi.af.1372@gmail.com

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

Rafsanjan University of Medical Sciences

Full name of responsible person

Mehdi Afshari nasab

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Biochemistry

Street addressDepartment of Biochemistry, Rafsanjan University of
Medical Sciences**City**

Rafsanjan

Province

Kerman

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 ProtocolUndecided - 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 ReportUndecided - 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