

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of aqueous *Berberis integerrima* extract on fatty liver and triglyceridemia in patients with fatty liver and hypertriglyceridemia

Protocol summary

Study aim

Medicinal plants with regarding benefit effects traditionally had special role in health of society. So, this study was done to evaluate the effect of *Berberis integerrima* extract on hypertriglyceridemia and fatty liver disease improvement.

Design

Clinical trial with pre- post control.

Settings and conduct

Mofatteh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Inclusion criteria of patients are tree times of blood experiment for triglyceride and sonography response for patients with fatty liver. Total patients with hypertriglyceridemia including males and females with 20-70 age range is essential for inclusion to study. exclusion criteria: Out of ranges 20-70 years. Sectional increase of triglyceride. Individuals which had not compliance for administration in duration of study for regularly *Berberis integerrima* extract.

Intervention groups

Barberry plant is considered as one of the vegetation cover of mountainous regions of Iran. In all parts of this plant, there are alkaloid berberin, oxyacantine and briamine. Due to the beneficial effects of black barberry on a variety of physical disorders, the traditional medicine recommends the use of black barberry in liver problems. So, in this study, the effect of barberry extract on triglyceride decrease and its action for the treatment of fatty liver will evaluate.

Main outcome variables

Fatty liver, triglyceride

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190220042772N1**

Registration date: **2019-03-15, 1397/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-15, 1397/12/24**

Update count: **0**

Registration date

2019-03-15, 1397/12/24

Registrant information

Name

Mousalreza Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3627 1622

Email address

r.mohamadi@iauvaramin.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-10-06, 1397/07/14

Actual recruitment start date

2019-03-03, 1397/12/12

Actual recruitment end date

2019-11-05, 1398/08/14

Trial completion date

2020-01-05, 1398/10/15

Scientific title

Effect of aqueous *Berberis integerrima* extract on fatty liver and triglyceridemia in patients with fatty liver and hypertriglyceridemia

Public title

Berberis integerrima effect on fatty liver and triglyceride

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria of patients are three times of blood experiment for triglyceride and sonography response for patients with fatty liver. Total patients with hypertriglyceridemia including males and females. 20-70 age range is essential for inclusion to study.

Exclusion criteria:

Out of ranges 20-70 years. Sectional increase of triglyceride Individuals which had not compliance for administration of permanently Berberis integerrima extract. (Duration of study)

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Actual sample size reached: **188**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Varamin-Pishva Branch

Street address

University street, Naghsh Jahan Town,

City

Varamin, Pishva

Province

Tehran

Postal code

3381774895

Approval date

2016-05-21, 1395/03/01

Ethics committee reference number

IR. IAU. Varamin. REC.1395,3

Health conditions studied

1

Description of health condition studied

Hypertriglyceridemia

ICD-10 code

E78.1

ICD-10 code description

Pure hyperglyceridaemia, Endogenous hyperglyceridaemia

2

Description of health condition studied

Fatty liver

ICD-10 code

k76.0

ICD-10 code description

Nonalcoholic fatty liver disease

Primary outcomes

1

Description

patients with hypertriglyceridemia

Timepoint

Measurement of triglyceride value before consumption of Berberis integerrima extract and two months after daily consumption of Berberis integerrima extract.

Method of measurement

triglyceride kit

2

Description

Patients with non- alcoholic fatty liver disease

Timepoint

Evaluation of fatty liver before consumption of Berberis integerrima extract and two months after daily consumption of its.

Method of measurement

sonography devise

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Berberis integerrima extract consumption

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofatteh Hospital

Full name of responsible person

Seyed Mosaal-Reza Mohammadi

Street address

No 3, Mofatteh Hospital, Imam Reza Blvd, Razi Sq, Varamin

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mofateh@sbmu.ac.ir

Web page address

<http://mvmc.sbmu.ac.ir/index.jsp?pageid=8050&p=1>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Paiman Azizi

Street address

Naghsh Jahan Town, Pishva, Islamic Azad University

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74895 33817

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lauvaramin@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

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**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Seyed Mosaalreza Mohammadi

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Microbiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mousalreza Mohammadi

Position

instructor

Latest degree

Master

Other areas of specialty/work

Biochemistry

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mosaalreza Mohammadi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Participant data are to be shared after deidentified.

When the data will become available and for how long

Data will be available in May 2019

To whom data/document is available

All peoples can apply for receiving data.

Under which criteria data/document could be used

Statistical analysis and evaluation of diet regimen are allowed.

From where data/document is obtainable

The applicant should refer to Mr. Mohammadi , department of Islamic Azad University, Varamin Branch, by emailr.mohammadi888@yahoo.com.

What processes are involved for a request to access data/document

The applicants will receive data after confirmation after three weeks.

Comments