

# 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

**City**

Varamin

**Province**

Tehran

**Postal code**

3381774457

**Phone**

+98 21 3622 3011

**Email**

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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Varamin

**Province**

Tehran

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74895 33817

**Phone**

+98 21 3672 6955

**Email**

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

**Street address**

No 27, Beheshti Blvd, Varamin

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**Province**

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74259 33817

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r.mohammadi888@yahoo.com

### 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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Pishva, Naghsh Jahan Town

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### Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Instructor

**Latest degree**

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**Other areas of specialty/work**

Biochemistry

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**Phone**

+98 21 3672 6955

**Email**

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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**