

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The effect of grape seed extract supplementation on glycemic status, lipid profile, plasma atherogenic index, liver enzymes, anthropometric indices and some inflammatory and antioxidant indices in overweight and obese patients with nonalcoholic fatty liver disease

#### Protocol summary

##### Study aim

Evaluation of the effect of grape seed extract on biochemical and anthropometric factors in patients with non-alcoholic fatty liver

##### Design

Clinical trials phase 2, two parallel groups, double-blind, randomized.

##### Settings and conduct

It is performed in the clinic of Shohada hospital in Hindijan. Researchers and patients are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-60 years old patient with non alcoholic fatty liver disease; BMI equal to 25-30.

Exclusion criteria: patients who have diabetes, cardiovascular, kidney and other hepatic diseases; pregnant or lactating women; smoking; alcohol consumption; use of dietary supplements

##### Intervention groups

Treatment group: Receiving grape seed extract 500 mg daily. Control group: receiving placebo.

##### Main outcome variables

Changes in biochemical factors (HDL, LDL, ALT, AST, triglyceride, cholesterol, plasma atherogenic index, total antioxidant capacity, interleukin 6, fasting blood sugar, HbA1c, fasting insulin level, weight, body mass index, waist circumference)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190731044392N1**

Registration date: **2022-03-30, 1401/01/10**

Registration timing: **prospective**

Last update: **2022-03-30, 1401/01/10**

Update count: **0**

##### Registration date

2022-03-30, 1401/01/10

##### Registrant information

###### Name

Hamidreza Razmi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3615 7946

###### Email address

hamidrezazarzmi95@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-06-22, 1401/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of grape seed extract supplementation on glycemic status, lipid profile, plasma atherogenic index, liver enzymes, anthropometric indices and some inflammatory and antioxidant indices in overweight and obese patients with nonalcoholic fatty liver disease

##### Public title

Effect of Grape seed extract in treatment of fatty liver

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

20-60 years old patient with non alcoholic fatty liver disease

### Exclusion criteria:

Patients who have diabetes, cardiovascular, kidney and other hepatic diseases Pregnant or lactating women Smoking Alcohol consumption Use of dietary supplements

## Age

From **20 years** old to **60 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The present study is a simple randomized clinical trial on subjects with fatty liver. In this study, individuals are divided into two groups of drugs and placebo. The method of assigning subjects to each group is that individuals are assigned every other one.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

First, researchers will explain the study to the participants. This study is a triple-blind study. The two groups, medications and placebo, receive completely similar capsules, and they do not know the contents of the capsule. The statistical analyzer is not informed about the groups. Also, the therapist will not know about the intervention groups.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahvaz Jundishapur University of Medical sciences

##### Street address

Ahvaz Jondishapur University Of Medical Sciences,  
Golestan Ave. Ahvaz

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6165777696

#### Approval date

2022-03-14, 1400/12/23

#### Ethics committee reference number

IR.AJUMS.REC.1400.704

## Health conditions studied

### 1

#### Description of health condition studied

Non Alcoholic Fatty liver Disease

#### ICD-10 code

K76.0

#### ICD-10 code description

Fatty (change of) liver, not elsewhere classified

## Primary outcomes

### 1

#### Description

Aspartate aminotransferase

#### Timepoint

Before intervention and 2 months after intervention

#### Method of measurement

Blood test

### 2

#### Description

Alanine aminotransferase

#### Timepoint

Before intervention and 2 months after intervention

#### Method of measurement

Blood test

### 3

#### Description

Interlukine-6

#### Timepoint

Before intervention and 2 months after intervention

#### Method of measurement

Blood test

### 4

#### Description

Total antioxidant capacity

#### Timepoint

Before intervention and 2 months after intervention

#### Method of measurement

Blood test

## 5

### **Description**

Total cholesterol

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Blood test

## 6

### **Description**

LDL-C

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Blood test

## 7

### **Description**

HDL-C

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Blood test

## 8

### **Description**

Triglyceride

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Blood test

## 9

### **Description**

Atherogenic index of plasma

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Formula

## 10

### **Description**

Fasting blood sugar

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Blood test

## 11

### **Description**

Hemoglobin A1c

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Blood test

## 12

### **Description**

Insulin

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Blood test

## 13

### **Description**

Weight

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Digital scale

## 14

### **Description**

Body mass index

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

Body weight in kilograms divided by height squared in meters

## 15

### **Description**

Waist circumference

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

By measuring tape according to meter

## 16

### **Description**

Hip circumference

### **Timepoint**

Before intervention and 2 months after intervention

### **Method of measurement**

By measuring tape according to meter

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Daily intake of 260 mg grape seed extract supplement (twice a day and two tablets equivalent to 2.5 g each time) for 60 days

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Recipient of two 1 g placebo tablets (containing cellulose, silicon dioxide and starch) per day for 2 months

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hindijan Shohada Hospital

**Full name of responsible person**

Hamidreza Razmi

**Street address**

Hindijan Shohada Hospital, Chamran Blvd

**City**

Hindijan

**Province**

Khuzestan

**Postal code**

6165777696

**Phone**

+98 61 3333 3050

**Email**

hamidrezarazmi95@gmail.com

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Mehrnoosh Zakerkish

**Street address**

Ahvaz Jondishapur University Of Medical Sciences,  
Golestan Ave. Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6165777696

**Phone**

+98 61 3333 3050

**Email**

zakerkishm@yahoo.com

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Hamidreza Razmi

**Position**

PhD Student in Nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

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Golestan Ave. Ahvaz

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**Province**

Khuzestan

**Postal code**

6165777696

**Phone**

+98 61 3333 3050

**Email**

hamidrezarazmi95@gmail.com

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Ahmad Zare Javid

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ahvaz Jondishapur University of Medical Sciences,  
Golestan Ave. Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6165777696

**Phone**

+98 61 3333 3050

**Email**

ZareJavid-a@ajums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Hamidreza Razmi

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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Golestan Ave. Ahvaz

**City**

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**Province**

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**Postal code**

6165777696

**Phone**

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**Email**

hamidrezarazmi95@gmail.com

## 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**

Yes - There is 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

**Title and more details about the data/document**

All data can be shared after the participants in the study are unrecognizable.

**When the data will become available and for how long**

The data access period after printing the article.

**To whom data/document is available**

The data in this study will be available to researchers working at academic and scientific institute.

**Under which criteria data/document could be used**

Any analysis can be done with the consent of the main researcher.

**From where data/document is obtainable**

Hamidreza Razmi

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

The researcher or pharmaceutical company can send their request to the email after sending the documents to confirm their original identity. The project manager will then provide the requested information to the researcher or pharmaceutical company after ensuring the accuracy of the submitted documents after a period of one week.

**Comments**