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
hamidrezarazmi95@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

Khouzestan

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 cholestrol
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
Triglyciride
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

Khouzestan

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

Khouzestan

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

Ahvaz Jondishapur University of Medical Sciences, Golestan Ave. Ahvaz

City

Ahvaz

Province

Khouzestan

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

Khouzestan

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

Street address
Ahvaz Jondishapur University of Medical Sciences, Golestan Ave. Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6165777696

Phone
+98 61 3333 3050

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