

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the effect of grape seed extract on blood pressure and some serum antioxidant indices in patients with non-alcoholic fatty liver disease

Protocol summary

2022-08-19, 1401/05/28

Study aim

Investigating the effect of grape seed extract on blood pressure and some serum antioxidant indices in patients with non-alcoholic fatty liver disease in Hendijan city.

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 quality of life, biochemical factors (malondialdehyde, catalase, glutathione peroxidase, superoxide dismutase)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190731044392N2**

Registration date: **2022-08-19, 1401/05/28**

Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**

Update count: **0**

Registration date

Registrant information

Name

Hamidreza Razmi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-27, 1401/08/05

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of grape seed extract on blood pressure and some serum antioxidant indices in patients with non-alcoholic 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
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

2022-08-10, 1401/05/19

Ethics committee reference number

IR.AJUMS.REC.1401.183

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

Weight

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Digital scale

2

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

3

Description

Quality of life

Timepoint

Before intervention and 2 months after intervention

Method of measurement

SF-36 Questionnaire

4

Description

Malondialdehyde

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Blood test

5

Description

Catalase

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Blood test

6

Description

Glutathione Peroxidase

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Blood test

7

Description

Superoxide dismutase

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Blood test

8

Description

Waist circumference

Timepoint

Before intervention and 2 months after intervention

Method of measurement

By measuring tape according to meter

9

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 consumption of 260 mg grape seed extract supplement by Shari company (twice a day and each time one tablet equal to 2.5 grams) for 60 days orally, with morning and evening snacks.

Category

Treatment - Drugs

2

Description

Control group: recipient of two placebo tablets of 1 gram made in pharmacy faculty of Ahvaz Jundishapur University (containing cellulose, silicon dioxide and starch) for 60 days, orally with morning and evening snacks

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

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mehrnoosh Zakerkish

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Ahmad Zare Javid

Position

Associate professor

Latest degree

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Other areas of specialty/work

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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

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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

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