

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation the effect of Grapex on serum biochemical factors in Non-alcoholic Fatty Liver Disease

Protocol summary

Study aim

Evaluation of the effect of Grapex on biochemical factors in fatty liver patients.

Design

Clinical trials phase2, Two parallel groups, double-blind, randomized.

Settings and conduct

It is performed in the clinic of Shahid Beheshti hospital in Abadan. Researchers and patients are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Fatty liver disease, BMI equal to 30-40.

Exclusion criteria: Sensitivity to Grapex capsules.

Intervention groups

Treatment group: Receiving Grapex 200 mg daily.

Control group: Receiving placebo

Main outcome variables

Alternation on biochemical factors (ALT, AST enzymes, Triglyceride, Cholesterol, HDL, LDL, Antioxidant total capacity) in fatty liver patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200921048783N2**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **prospective**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

Registration date

2021-07-22, 1400/04/31

Registrant information

Name

Hoda Mojiri-Forushani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5326 5361

Email address

dr.mojiri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of Grapex on serum biochemical factors in Non-alcoholic Fatty Liver Disease

Public title

Effect of Grape seed extract in treatment of fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with fatty liver BMI equal to 30-40

Exclusion criteria:

Unwilling to enter the study Sensitivity to Grapex capsules

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

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)

Double blinded

Blinding description

First, researchers will explain the study to the participants. This study is a double-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.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical committee of Abadan University of Medical Sciences

Street address

Zolphaghari Ave,

City

Abadan

Province

Khuzestan

Postal code

6319811154

Approval date

2018-05-23, 1397/03/02

Ethics committee reference number

IR.ABADANUMS.REC.1397.008

Health conditions studied**1****Description of health condition studied**

Fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

Aspart amino transferase

Timepoint

Beginning of the study and 2 months after treatment

Method of measurement

Blood sample

2**Description**

Alanin amino transferase

Timepoint

Beginning of the study and 2 months after treatment

Method of measurement

Blood sample

3**Description**

Triglyceride

Timepoint

Beginning of the study and 2 months after treatment

Method of measurement

Blood sample

4**Description**

Cholesterol

Timepoint

Beginning of the study and 2 months after treatment

Method of measurement

Blood sample

5**Description**

High density lipoprotein

Timepoint

Beginning of the study and 2 months after treatment

Method of measurement

Blood sample

6**Description**

Low density lipoprotein

Timepoint

Beginning of the study and 2 months after treatment

Method of measurement

Blood sample

7

Description

Antioxidant total capacity

Timepoint

Beginning of the study and 2 months after treatment

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment and receiving Grapex capsule (Grape seed extract) 200 mg daily for 2 months.

Category

Treatment - Drugs

2

Description

Control group: Receiving placebo capsule daily for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Abadan clinic of Shahid Beheshti hospital

Full name of responsible person

Hoda Mojiri-Forushani

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Abadan university of Medical Sciences, Beginning of the 3 meters Ave, Zolfaghari street, Abadan City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

Sara Mobarak

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Abadan 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

Abadan University of Medical Sciences

Full name of responsible person

Hoda Mojiri-Forushani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

Hoda Mojiri-Forushani

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

The researcher or pharmaceutical company can send their request to the academic 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