Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 biochemicals 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

2

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
Khouzestan
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 mounths.
Category
Treatment - Drugs

2

Description
Control group: Receiving placebo capsule daily for 2 mounts.
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
Street address
Abadan university of Medical Sciences, Begining of the 3 meters Ave, Zolfaghari street, Abadan City
City
Abadan
Province
Khouzestan
Postal code
6319811154
Phone
+98 61 5338 4004
Fax
+98 61 5338 4008
Email
dr.mojiri@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abadan University of Medical Sciences
Full name of responsible person
Sara Mobarak
Street address
Abadan University of Medical Sciences, Beginning of the 30 meter Ave, Zolfaghari Street, Abadan city0
City
Abadan
Province
Khouzestan
Postal code
6319811154
Phone
+98 61 5338 4004
Fax
+98 61 5338 4008
Email
s.mobarak@abadanums.ac.ir
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
Street address
Abadan University of Medical Sciences, Beginning of 30 meter Ave, Zolfaghari Street, Abadan city
City
Abadan
Province
Khouzestan
Postal code
6319811154

Phone
+98 61 5338 4004
Fax
+98 61 5338 4008
Email
dr.mojiri@yahoo.com

Person responsible for scientific 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
Street address
Abadan University of Medical Science, Beginning of the 30 meter Ave, Zolfaghari Street, Abadan city
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Province
Khouzestan
Postal code
6319811154
Phone
+98 61 5338 4004
Fax
+98 61 5338 4008
Email
dr.mojiri@yahoo.com

Person responsible for updating data

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
Street address
Abadan University of Medical Sciences, Beginning of 30 meter Ave, Zolfaghari Street, Abadan city
City
Abadan
Province
Khouzestan
Postal code
6319811154
Phone
+98 61 5338 4004
Fax
+98 61 5338 4008
Email
dr.mojiri@yahoo.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
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