Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

The efficacy of Omega3 in treatment of Non-Alcoholic Fatty Liver Disease

Protocol summary

Summary

The patient randomized divided to two groups: control and intervention. At start of study the patient of both groups evaluated as personal data, past medical history, age, height, BMI, tmie for exercise in day, diet, and lab data:TSH, lipid profile, LFT, FBS. For control group treatment is increase activity, diet low fat, Liver support drugs, vitE, Metformin. For trial group treatment is like control group plus omega3 2gr in day(cap 1gr BID include EPA 180:DHA 120).The patient treatment for 3 month and observe at treatment duration and again evaluated with BMI, ALT, AST at the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052313427N1**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name
Amin Kargar
Name of organization / entity
Fasa university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Fasa University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Omega3 in treatment of Non-Alcoholic Fatty Liver Disease

Public title

Omega 3 on fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

The patient who diagnosed as fatty liver disease by increase in ALT and AST and liver ultrasonography with 4 criteria of sonography added to intervention.The patient who hasn't sign the permission form, or drink ethanol more than 20 gram in a day or take some drugs that cause of fatty liver such as steroids,sterogen,amiodaron,tamoxifen in 6 month ago and patient who has Hepatit B and C,auto immune hepatitis, wilson, hemachromatosis, decrease of alpha-1-antitripsin or sever disease such as heart, liver, psychology disease was eliminated.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Fasa university of medical sciences
Street address
Fasa-Ebne sina Square-Fasa university of medical sciences
City
Fasa
Postal code
7461686688
Approval date
2012-11-21, 1391/09/01
Ethics committee reference number
e0192

Health conditions studied

1

Description of health condition studied
Fatty (change of) liver
ICD-10 code
K76.0
ICD-10 code description
Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes

1

Description
Fatty liver
Timepoint
Before intervention, 3 months after intervention
Method of measurement
AST, ALT(liver enzymes)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group get Omega3 2 gram per day (cap 1000mg (EPA 180: DHA 120)) for 3 months with other treatment have given to control group. Control group: increase activity, diet, Vit E, Liver support and metformin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Street address
City
Fasa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Dr. Bahram ali
Street address
Fasa
City
Fasa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fasa University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty