

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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, time 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

Country

Iran (Islamic Republic of)

Phone

+98 73 1222 0995

Email address

aminkargar5@yahoo.com

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 Hepatitis B and C, auto immune hepatitis, wilson, hemochromatosis, 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

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Amin Kargar
Position
Intern
Other areas of specialty/work
Street address
Fassa
City
Fassa
Postal code
Phone
+98 73 1222 0995
Fax
Email
aminkargar5@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Dr. Kazemeyni
Position
Attending in GI disease
Other areas of specialty/work
Street address
Fassa
City
Fssa
Postal code

Phone
+98 73 1222 0995
Fax
Email
kazemini@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Amin Kargar
Position
Intern
Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
aminkargar5@yahoo.com
Web page address

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