Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Comparison the effect of ezetimibe and acarbose on biochemical indices in patient with nonalcoholic fatty liver disease

Protocol summary

Summary

The aim of this study was to evaluate the efficacy of acarbose (alafa glicosidase inhibitor) and ezetimibe (NPC1L1 inhibitor, a lipid-lowering agent) as new therapeutic approaches for treatment of non-alcoholic fatty liver disease. This study was the second phase of a double blind randomized clinical trial. A total of 62 ultrasonograghic proven NAFLD patient with elevated liver enzymes assigned into 2 groups. The patients with concomittent liver disease, chronic hepatitis or alcohol consumption more than 20 gr per day excluded from this study. In acarbose group patients received 50 mg acarbose 3 times per day and the ezetimibe group received 10 mg ezetimibe per day. The duration of study was two months. Liver enzymes, insulin resistance index, serum lipids, BMI and CRP were measured before and after administration of the drugs and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109197590N1**
Registration date: **2011-12-23, 1390/10/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-12-23, 1390/10/02

Registrant information

Name

Foroogh Alborzi Avanaki

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1333 2932

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of ezetimibe and acarbose on biochemical indices in patient with nonalcoholic fatty liver disease

Public title

The effect of ezetimibe and acarbose in treatment of non alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- the patients diagnosed by means of ultrasound (Bright liver pattern with liver kidney contrast); 2-ALT more than 40 in men and more than 31 in women; 3-Age above18. Exclusion criteria: 1-Type1 or 2 diabetes mellitus; 2-Positive serology for hepatitis; 3-Alcohol consumption more than 20gr per day; 4-History of renal or liver disease; 5-Using drugs like steroids or drugs that influence energy metabolism, intestinal transit, substrate metabolism.

Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **31**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Science, Bahonar blvd
City
Qazvin
Postal code
Approval date
2011-04-27, 1390/02/07
Ethics committee reference number
28/20/4415

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

Primary outcomes

1

Description
Liver enzyme, AST, aspartate aminotransferase
Timepoint
Before and 2 months after treatment
Method of measurement
Lab kit

2

Description
Liver enzyme, ALT, alanine aminotransferase
Timepoint
Before and 2 months after treatment
Method of measurement
Lab kit

Secondary outcomes

1

Description
Insulin resistance index
Timepoint
Before and 2months after treatment
Method of measurement
Fasting glycemia mmol/L× fasting insulinemiaMIU/L/22 .lab kit

2

Description
Inflamation index hs CRP
Timepoint
Before and 2 months after treatment
Method of measurement
Lab kit

Intervention groups

1

Description
50 mg acarbose 3 times per day, oral, in acarbose group
Category
Treatment - Drugs

2

Description
10 mg ezetimibe once per day, oral, in ezetimibe group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Buali sina hospital.
Full name of responsible person
Dr Foroogh Alborzi Avanaki
Street address
Bualisina hospital

City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Qazvin University of Medical Sciences
Full name of responsible person
Dr Mahnaz Abbasi
Street address
Bahonar blvd.
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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
Vice chancellor for research, Qazvin 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
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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