

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Compare of orlistat and metformin in the treatment of fatty liver disease in non-diabetic patients

Protocol summary

Summary

Due to the high sensitivity of the disease and few studies in this field, the object of this study was to compare the effect of Orlistat and Metformin in the treatment of fatty liver disease in patients without diabetes mellitus. The method: This study was designed for 12 to 15 weeks and clinical trial. 100 non-diabetic patients with fatty liver disease were referred to Imam Khomeini hospital clinics, are selected. Patients are divided into 2 groups A and B. Group A are patients that 50 people will be prescribed Metformin and that 50 people are in Group B will be prescribed Orlistat. Vitamins or other nutrients will not be prescribed. Considered in all patients (demographic, etc.) Will respond. Blood samples will be collected before and after treatment. Also patients before and after treatment will be examined by ultrasound sonographer. Ultrasound study, each patient before and after each patient by a sonographer and the tests will be carried out by a laboratory center. Eventually the two groups in terms of improving liver function checked. The two groups were compared in terms of better grade. Inclusion criteria for the study: Having Nonalcoholic fatty liver disease, the absence of diabetes mellitus, Fatty liver grade 2 and above, not having severe systemic disease, Lack of viral and autoimmune hepatitis, Lack of thyroid disease, do not have hyper triglyceridemia. Exclusion criteria: Having severe systemic disease, having viral hepatitis and autoimmune, having thyroid disease, Hyper triglyceridemia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031827097N1**

Registration date: **2016-06-05, 1395/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

Name

Dr Faramarz Darghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardebil University of Medical Sciences

Expected recruitment start date

2016-03-05, 1394/12/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare of orlistat and metformin in the treatment of fatty liver disease in non-diabetic patients

Public title

The effect of orlistat and metformin in the treatment of fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

(Inclusion criteria: Having Nonalcoholic fatty liver disease, the absence of diabetes mellitus, Fatty liver grade 2 and above, not having severe systemic disease, Lack of viral and autoimmune hepatitis, Lack of thyroid disease, do not have hyper triglyceridemia and Exclusion criteria: Having severe systemic disease, having viral hepatitis and autoimmune, having thyroid disease, Hyper triglyceridemia)

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ardebil University of Medical Sciences

Street address

Ardebil University of Medical Sciences, University street, Ardabil, Iran

City

Ardebil

Postal code**Approval date**

2016-02-24, 1394/12/05

Ethics committee reference number

IR.ARUMS.REC.1394.87

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

Fatty liver

ICD-10 code

(K75.8)

ICD-10 code description

nonalcoholic steatohepatitis

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

Triglyceride of blood

Timepoint

Before and after the study

Method of measurement

Milligrams per deciliter

Secondary outcomes

empty

Intervention groups**1****Description**

Tablet Metformin 1000mg once in a day for 3 months

Category

Treatment - Drugs

2**Description**

Tablet Orlistat 120mg once in a day for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomini Hospital

Full name of responsible person

Dr babak shirinzadeh

Street address**City**

Ardabil

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ardebil University of Medical Sciences

Full name of responsible person

Dr shahram habibzadeh

Street address

Ardebil University of Medical Sciences, University street, Ardabil, Iran

City

Ardabil

Grant name**Grant code / Reference number**

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

Yes

Title of funding source

Ardebil 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**

Ardebil University of Medical Sciences

Full name of responsible person

Dr Iranparvar

Position

Subspecial

Other areas of specialty/work**Street address**

Imam khomini hospital, Ardabil, Iran

City

Ardabil

Postal code**Phone**

+98 914 415 0700

Fax**Email**

m.iranparvar@arums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ardebil University of Medical Sciences

Full name of responsible person

Dr Yazdanbod

Position

Subspecial

Other areas of specialty/work**Street address**

Imam Khomini Hospital, Ardabil, Iran

City

Ardabil

Postal code**Phone**

+98 910 407 0448

Fax**Email**

A.yazdanbod@arums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ardebil University of Medical Sciences

Full name of responsible person

Dr babak shirinzhadeh

Position

Internal Medicine Assistant

Other areas of specialty/work**Street address**

Ardebil University of Medical Sciences, University street, Ardabil, Iran

City

Ardabil

Postal code**Phone**

+98 914 151 3568

Fax**Email**

naghizadeh73@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