

# 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 Darghahi

###### 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 Khomeini Hospital

**Full name of responsible person**

Dr babak shirinazadeh

**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*