

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Compare the therapeutic effect of metformin, pioglitazone and vitaminE E in patients with non-alcoholic fatty liver disease

#### Protocol summary

##### Summary

The present study aim to compare the therapeutic effect of metformin, pioglitazone and vitaminE E in patients with non-alcoholic fatty liver disease. in this study, 93patients with the diagnosis of NAFLD(according to sonographic findings), referred to the Imam-Reza Hospital,Kermanshah during 2009-2011, after obtaining informed consent from participation in the study, were randomly divided into three groups. Then,the three groups received the following treatment regimens for 12weeks: one group received metformin (2gr daily),the second group received pioglitazone(30mg daily)and the third group took vitaminE (800IU daily). Before initiation of the experiment and at the end of treatment course,liver function tests(LFTs), body mass index(BMI), insulin resistance index(HOMA-IR), fasting blood sugar and serum level of insulin were measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016010411991N3**

Registration date: **2016-01-22, 1394/11/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-01-22, 1394/11/02

##### Registrant information

##### Name

Azam Sharifi

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3836 1266

##### Email address

azamsharifi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2009-05-22, 1388/03/01

##### Expected recruitment end date

2011-11-21, 1390/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Compare the therapeutic effect of metformin, pioglitazone and vitaminE E in patients with non-alcoholic fatty liver disease

##### Public title

Effect of metformin, pioglitazone and vitaminE E in patients with non-alcoholic fatty liver disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with non-alcoholic fatty liver disease according to sonographic findings; Having age between 17 to 50 years; Having negative serology of viral hepatitis; Willingness to participate in the study. Exclusion criteria: having obvious presentations of hepatic diseases; history of jaundice; taking steroids; alcohol drinking; diabetes; pregnancy; hypothyroidism; renal failure.

##### Age

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 93

**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**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah.

**City**

Kermanshah

**Postal code****Approval date**

2009-05-26, 1388/03/05

**Ethics committee reference number**

87010

**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, not elsewhere classified

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

severity of fatty liver

**Timepoint**

before and 12 weeks after the interventions

**Method of measurement**

according to echogenicity of the liver and its comparison with the adjacent kidney, and also comparison with echogenicity of the spleen, and the view of diaphragm and perivascular region of the intrahepatic vessels.

2**Description**

serum level of liver function tests (AST, ALT, Alkp)

**Timepoint**

before and 12 weeks after the interventions

**Method of measurement**

(IU/l) by diagnostic laboratory kits (Pars Azmoon, Iran) and the auto analyzer (Hitachi 902)

**Secondary outcomes**1**Description**

body mass index(BMI)

**Timepoint**

before and 12 weeks after the interventions

**Method of measurement**(Kg/m<sup>2</sup>)2**Description**

insulin resistance index(HOMA-IR)

**Timepoint**

before and 12 weeks after the interventions

**Method of measurement**

[fasting glucose (mg/dl) × insulin (μU/ml)]/ 405

3**Description**

fasting blood sugar

**Timepoint**

before and 12 weeks after the interventions

**Method of measurement**

mg/dl by diagnostic laboratory kits (Pars Azmoon, Iran) and the auto analyzer (Hitachi 902)

4**Description**

serum level of insulin

**Timepoint**

before and 12 weeks after the interventions

**Method of measurement**

(μu/ml) by Monobind ELISA kit (Monobind, USA)

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

Intervention group: metformin2 gr daily, orally for 12

weeks

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Pioglitazone30 mg dially, orally for12 weeks

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group: vitamin E 800 IU daily, orally for 12 weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam-Reza Hospital,Kermanshah

**Full name of responsible person**

Karoon Shahebrahimi

**Street address**

Imam-Reza Hospital, Bagh-e Abrisham, Kermansh, Iran.

**City**

Kermanshah

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research,Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti BLV, Kermanshah

**City**

Kermanshah

**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,Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Karoon Shahebrahimi

**Position**

Faculty of Medicine

**Other areas of specialty/work**

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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*