Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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)

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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 criteriain: 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 Univesity 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/m2)

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/dlby 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 for12

weeks

Category

Treatment - Drugs

2

Description

Intervention group: Pioglitazone30 mg dialy, 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

Street address

Emam Reza hospital, Sorkhelijeh boulevard, Kermanshah

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kshahebrahimi@gmail.com

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Person responsible for scientific inquiries

Contact

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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