

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

Comparison of therapeutic effects of metformin, pioglitazone and vitamin E on nonalcoholic fatty liver disease patients

Protocol summary

Summary

Aim: comparison of the therapeutic effects of metformin, pioglitazone and vitamin E in patients with Non-alcoholic fatty liver disease (NAFLD). Methods: In this clinical trial, 93 patients in Imam Reza Hospital, Kermanshah, diagnosed with NAFLD (finding on ultrasonography) were randomly divided into three groups. Patients randomized into study groups by 1:1 ratio method using a computer-generated random numbers. Inclusion criteria: Age above 18 year and Non-alcoholic fatty liver disease alone with negative hepatitis serology. Exclusion criteria: clinical manifestation of liver disease, icter, steroid and alcohol use, diabetes, pregnancy, hypothyroidism, renal failure. Each group received group A: 2 gr/daily metformin, group B: 30 mg/daily pioglitazone, group C, 800 IU/daily vitamin E for 12 weeks. Liver function tests, body mass index, hemostatic assessment model, blood glucose and insulin levels were measured before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071313069N2**

Registration date: **2013-09-22, 1392/06/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Mohammad Rasoul Ghadami

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6310

Email address

mrghadami@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2007-06-06, 1386/03/16

Expected recruitment end date

2009-11-07, 1388/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of metformin, pioglitazone and vitamin E on nonalcoholic fatty liver disease patients

Public title

Comparison of metformin, pioglitazone and vitamin E on nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age above 18 year and Non-alcoholic fatty liver disease alone with negative hepatitis serology
Exclusion criteria: clinical manifestation of liver disease, icter, steroid and alcohol use, diabetes, pregnancy, hypothyroidism, renal failure.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 93

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Patients randomized into study groups by 1:1 ratio method using a computer-generated random numbers. Physician who evaluates patients is blind to treatment interventions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd. Build no. 2

City

Kermanshah

Postal code

Approval date

2013-02-15, 1391/11/27

Ethics committee reference number

7/420/53475/پ

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver enzymes, Blood sugar, Insulin

Timepoint
Before and 12 weeks after treatment

Method of measurement
Laboratory assessment (ELISA)

Secondary outcomes

1

Description

Liver echo pattern

Timepoint

Before and 12 weeks after treatment

Method of measurement

Sonographic assessment

Intervention groups

1

Description

Group A: Tablet metformine 2gr/day orally (two 500 mg tablets q 12h) for 12 weeks

Category

Treatment - Drugs

2

Description

Group B: Tablet pioglitazone 30 mg/day orally (one 15 mg tablet q 12h) for 12 weeks

Category

Treatment - Drugs

3

Description

Group C: Tablet vitamin E 800 IU/day orally (One 400 IU tablet q 12h) for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Street address

Sorkheh lizheh

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

Dr. Farid Najafi

Street address

Build No. 2 of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

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

Dr. Mohammad Rasoul Ghadami

Position

General physician

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

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Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rasoul Ghadami

Position

General physician

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

Dr. Mohammad Rasoul Ghadami

Position

General physician

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

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City

Kermanshah

Postal code**Phone**

+98 83 1427 6310

Fax**Email****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