Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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)

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+98 83 1427 6310

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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
Shaihid 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
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Dr. Mohammad Rasoul Ghadami
Position
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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