

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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

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

**Full name of responsible person**

Dr. Mohammad Rasoul Ghadami

**Position**

General physician

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

Imam Reza Hospital, Sorkheh lizheh

**City**

Kermanshah

**Postal code****Phone**

+98 83 1427 6310

**Fax****Email**

mr\_ghadami@yahoo.com mrghadami@kums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Rasoul Ghadami

**Position**

General physician

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Dr. Mohammad Rasoul Ghadami

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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*