# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jun 2026

## Comparing the treatment effect of Pioglitazone with Metformin in patients with Non Alcoholic SteatoHepatitis (NASH)

## Protocol summary

**Summary**

Considering the importance of treating fatty liver disease, present study will be done to compare the therapeutic effects of pioglitazone with metformin. 80 nonalcoholic steatohepatitis (NASH) patients, with elevated liver enzymes, will be enrolled in the study after confirmation of fatty liver using ultrasonography. Patients will be divided into two 40-member groups in a randomized manner with Block Randomization. For treatment of fatty liver, metformin or Pioglitazone are prescribed for 4 months. Body weight, liver enzymes, Low density lipoprotein (LDL), High density lipoprotein (HDL), Triglyceride (TG), Total cholesterol (Chlo) and Fasting blood sugar (FBS) are evaluated before intervention, 2 months later and after finishing study in both groups. Also HOMA index (Homeostatic model assessment) index and Adiponectin are investigated before intervention and after finishing study in both groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201105026361N1**
Registration date: **2011-11-16, 1390/08/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2011-11-16, 1390/08/25

**Registrant information**

**Name**

Effat Taherkhani

**Name of organization / entity**

Kashan University Medical Siences and Health Services

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 5586 6211

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**Recruitment status**

**Recruitment complete**

**Funding source**

Kashan University of Medical Sciences and Health Services

**Expected recruitment start date**

2011-03-06, 1389/12/15

**Expected recruitment end date**

2011-12-21, 1390/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the treatment effect of Pioglitazone with Metformin in patients with Non Alcoholic SteatoHepatitis (NASH)

**Public title**

Comparison the treatment effect of Pioglithazone with Metformin in patients with Non Alcoholic SteatoHepatitis (NASH)

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: All patients with fatty liver disease based on sonography that have Aspartate aminotransferase (AST) and Alanine aminotransferase (ALT) more than normal (more than 40). Exclusion criteria: Alcohol consumption; drug induced hepatitis;

use of some drugs (corticosteroids, statins); Diabetes mellitus; Chronic viral hepatitis (B,C); Autoimmune hepatitis; Wilson disease; Hemochromatosis; Ischemic heart disease; Heart failure; Liver failure; liver mass; Pregnancy.

**Age**
From **21 years** old to **50 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Kashan University of Medical Sciences and Health Services

**Street address**
Medical college, Ghotb Ravandi boulevard

**City**
Kashan

**Postal code**
8715981151

**Approval date**
2011-01-10, 1389/10/20

**Ethics committee reference number**
2851/1/5/29/پ

## Health conditions studied

### 1

**Description of health condition studied**
Fatty liver

**ICD-10 code**
K76.0

**ICD-10 code description**
fatty (change of) liver, not elsewhere classified

## Primary outcomes

### 1

**Description**
FBS

**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)

**Method of measurement**
Device photometry

### 2

**Description**
TG

**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)

**Method of measurement**
Device photometry

### 3

**Description**
Chlo

**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)

**Method of measurement**
Device photometry

### 4

**Description**
HDL

**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)

**Method of measurement**
Device photometry

### 5

**Description**
LDL

**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)

**Method of measurement**
Device photometry

### 6

**Description**
AST

**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)

**Method of measurement**
Device photometry

**7**

**Description**
ALT
**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)
**Method of measurement**
Device photometry

**8**

**Description**
Alkp
**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)
**Method of measurement**
Device photometry

**9**

**Description**
Body weight
**Timepoint**
Before intervention, two months after intervention and end of intervention (four months after intervention)
**Method of measurement**
Balance

**10**

**Description**
HOMA Index
**Timepoint**
Before intervention and end of intervention (four months after intervention)
**Method of measurement**
fasting Glucose(mmol/L)*Insulin(microunit/ml)/22.5

**11**

**Description**
Serum Adiponectin
**Timepoint**
Before intervention and end of intervention (four months after intervention)
**Method of measurement**
Enzyme Linked Immunosorbent Assay (ELISA)

## Secondary outcomes

**1**

**Description**
Side effects of drug
**Timepoint**
before intervention, two months after intervention, end of intervention (four months after intervention)
**Method of measurement**
history, physical examination, plasma sampling

## Intervention groups

**1**

**Description**
Metformin: Tablet 500 mg, oral, BID, for 4 months.
**Category**
Treatment - Drugs

**2**

**Description**
Pioglitazone: Tablet 30 mg, oral, daily, for 4 months
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Private Clinic of Gastroentrology
**Full name of responsible person**
Dr. Seied Mohsen Razavizadeh
**Street address**
Third floor, Central medical building, opposite of mellat shopping centere, outset of Shahid Rajaee street
**City**
Kashan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Kashan University of Medical Sciences and Health Services
**Full name of responsible person**
Dr. Qolam Ali Hamidi
**Street address**
Medical college, Ghotb Ravandi boulevard
**City**
Kashan
**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, Kashan University of Medical Sciences and Health Services
**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*