Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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

Email address

razavizadeh_m@kaums.ac.ir

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
Kashan University of Medical Sciences and Health Services
Full name of responsible person
Dr. Seied Mohsen Razavizadeh
Position
Assistant professor
Other areas of specialty/work
Street address
Shahid Beheshti Hospital, Ghotb ravandi boulevard
City
Kashan
Postal code
87159/81151
Phone
+98 36 1555 0026
Fax
Email
razavizadeh_m@kaums.ac.ir , mohsen-razavizade@yahoo.com
Web page address
www.kaums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Siences and Health Services
Full name of responsible person
Dr. Seied Mohsen Razavizadeh
Position
Assistant Professor
Other areas of specialty/work
Street address
Shahid Beheshti Hospital, Ghotb ravandi boulevard
City
Kashan
Postal code
87159/81151
Phone
+98 36 1555 0026
Fax
Email
razavizadeh_m@kaums.ac.ir , mohsen-razavizade@yahoo.com
Web page address
www.kaums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Siences and Health Services
Full name of responsible person
Dr. Seied Mohsen Razavizadeh
Position
Assistant Professor
Other areas of specialty/work
Street address
Shahid Beheshti Hospital, Ghotb ravandi boulevard
City
Kashan
Postal code
87159/81151
Phone
+98 36 1555 0026
Fax
Email
razavizadeh_m@kaums.ac.ir , mohsen-razavizade@yahoo.com
Web page address
www.kaums.ac.ir

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