# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Nov 2026

## The comparison of metformin, pioglitazon and Silymarin on biochemical indices in patient with nonalcoholic fatty liver

## Protocol summary

**Summary**

The aim of our study is comparison of the effect of three different drugs: Pioglitazon and Metformin as insulin sensitizer, and silymarin as an anti oxidan in reduction of biochemical indices in patient with NASH. inclusion criteria were patients with NASH and exclusion criteria were DM, Alchole drinking, HBS Ag, HCV Ab.This randomized clinical trial lasted 2 mounths. 66 patient with NASH were divided randomly in three groups. Serum insulin, FBS, TG, Chol, AST and ALT were measured before and after treatment and BMI and HOMA index was calculated before and after treatment. The first group was treeted with Pioglitazon 15 mg, second group with Metformin 500mg and the third group with Silymarin 140 mg, daily. This study was double blind (Physision and patient).

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201105084849N2**
Registration date: **2011-05-28, 1390/03/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2011-05-28, 1390/03/07

**Registrant information**

**Name**

Amir Ziaee

**Name of organization / entity**

Metabolic Diseases Research Center, Qazvin University of Medical Sciences, Qazvin, Iran

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice- Cancellor for Reseserch of Medical University of Qazvin

**Expected recruitment start date**

2010-11-22, 1389/09/01

**Expected recruitment end date**

2011-01-21, 1389/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison of metformin, pioglitazon and Silymarin on biochemical indices in patient with nonalcoholic fatty liver

**Public title**

The comparison of metformin, pioglitazon and Silymarin on biochemical indices

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

inclusion criteria; patients with NASH; rising of AST and ALT; evidence of fatty liver in ultrasound and exclusion criteria; DM; Alchole drinking; HBS Ag; HCV Ab

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Qazvin University of Medical Science

**Street address**

Qazvin, Qazvin University of Medical Science

**City**

Qazvin

**Postal code**

**Approval date**

2011-11-28, 1390/09/07

**Ethics committee reference number**

28/20/4348

## Health conditions studied

### 1

**Description of health condition studied**

Nutritional and metabolic disorders in diseases classified elsewhere

**ICD-10 code**

E90*

**ICD-10 code description**

Nutritional and metabolic disorders in diseases classified elsewhere

## Primary outcomes

### 1

**Description**

FBS

**Timepoint**

2 months after first measuring

**Method of measurement**

blood sampling

## Secondary outcomes

### 1

**Description**

ALT

**Timepoint**

2 months after first measuring

**Method of measurement**

blood sampling

## Intervention groups

### 1

**Description**

administration of 500mg metformin daily for 2 months

**Category**

Treatment - Drugs

### 2

**Description**

administration of 15mg pioglitazone daily for 2 months

**Category**

Treatment - Drugs

### 3

**Description**

administration of 140mg silymarin daily for 2 months

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Clinic Of GI Diseases in Buali Hospital

**Full name of responsible person**

**Street address**

**City**

Qazvin

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice-Cancellor for Research of Qazvin University of Medical Science

**Full name of responsible person**

Dr Saeed Asefzade

**Street address**

Qazvin, Qazvin University of Medical Science

**City**

Qazvin

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice-Cancellor for Research of Qazvin University of Medical Science
**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

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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*