

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

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Name of organization / entity

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

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Iran (Islamic Republic of)

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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

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

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Qazvin, Qazvin University of Medical Science

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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

Contact

Name of organization / entity

Qazvin University of Medical Science

Full name of responsible person

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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