Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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

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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

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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

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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