

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the effectiveness of N-Acetylsyctein, Pioglitazon and Metformin in the treatment of non alcoholic fatty liver disease

Protocol summary

Summary

Purpose: With the use of different methods of treatment for the prevention and treatment of NAFLD in this study has compared 3 methods of treatment used in these patients should be done. Study design: The study was double-blind and randomized clinical trial population: patients with a diagnosis NAFLD referred to the gastroenterology clinic Main inclusion criteria: elevated liver enzymes more than 1.5 to 2 times normal. Or the presence of fatty liver include Grade 1 and above Main exclusion criteria: .Hepatitis B and hepatitis C (HBs Ag, HCV Ab) . Alcoholic liver disease (more than 20 grams of alcohol consumed more than 10 g in men and women) autoimmune liver disease, The use of drugs with liver toxicity during the last 6 months . severe systemic disease, metabolic liver disease, (Wilson - hemochromatosis -a1 antitrypsin) Sample size: 60 patients were assigned to three groups of 20 patients each were randomly divided . NAC 600 mg daily for the first group and the second group one gram daily of metformin and pioglitazone 30 mg administered to the third group. After 2 months patients will evaluate changes of liver enzymes and fatty liver ultrasound evidences. Finally, a comparison will be made of the three drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309188308N3**

Registration date: **2015-02-23, 1393/12/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-11-18, 1393/08/27

Expected recruitment end date

2015-03-18, 1393/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of N-Acetylsyctein, Pioglitazon and Metformin in the treatment of non alcoholic fatty liver disease

Public title

Treatment of NAFLD with N-Acetylsyctein, Pioglitazon and Metformin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Elevated liver enzymes > 1.5 times
2) Sonographic diagnosis of NAFLD (Grade 1 and more)

Exclusion criteria: 1) Viral hepatitis 2) Alcoholic liver disease 3) Autoimmune liver disease 4) Hepatotoxic drug use in the past 6 month 5) Systemic illness 6) Metabolic liver disease 7) Active drug abuse 8) Pregnancy 9) Diabetes mellitus

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Research Ethics committee

Street address

Hamedan University of Medical Scinces, Shahid fahmide street

City

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6517619651

Approval date

2013-06-12, 1392/03/22

Ethics committee reference number

D/P/16/35/9/1281

Health conditions studied

1

Description of health condition studied

Non Alcoholic Fatty Liver Disease

ICD-10 code

K75.8

ICD-10 code description

Nonalcoholic steatohepatitis

Primary outcomes

1

Description

Liver enzymes

Timepoint

two month

Method of measurement

Labratory

Secondary outcomes

1

Description

Grading of Steatosis

Timepoint

two month

Method of measurement

Sonography

Intervention groups

1

Description

Third group: metformin tablets 500 mg every 12 hours for two months

Category

Treatment - Drugs

2

Description

Second group pioglitazone 30 mg tablets for two months

Category

Treatment - Drugs

3

Description

First group: N-acetylcysteine 600 mg tablets for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Shahid Beheshti Hospital

Full name of responsible person

Dr.mehdi rezvan

Street address

shahid beheshti hospital.Eram avenu.Hamedan. Iran

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology
University of Medical Sciences of Hamedan

Full name of responsible person

Dr.mohammad yoosef alikhani

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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 Chancellor for Research and Technology University
of Medical Sciences of Hamedan

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**

University of Medical Sciences of Hamedan

Full name of responsible person

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Position

Internal Medicine residents

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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