Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Comparison of the effectivness 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 studylhas 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 pationts will evaluatesin changes of liverenzymesand 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

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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 effectivness 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
Hamedan

Postal code
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 Sciencesof Hamedan

Full name of responsible person
Dr.Mehdi.Rezvan

Position
Internal Medicine residents

Other areas of specialty/work

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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