

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Health impact of Melatonin, Metformin and Ursodeoxycholic acid in treatment of patients with Nonalcoholic Fatty Liver Disease (NAFLD)

Protocol summary

Summary

Objectives: The objective of this study is comparison of therapeutic effect of Melatonin, Metformin and Ursodeoxycholic acid with placebo in treatment of patients with Nonalcoholic Fatty Liver Disease (NAFLD).
Design: Patients with NAFLD who have proven steatosis by Fibroscan, during the double-blind randomized clinical trials are under treatment regimen. Setting and conduct: Patients divided into three groups and one control group. This pilot study would be with a sample size of 120. For the patients at the beginning and end of the project weight, height, waist circumference, BMI, Cholesterol, TG, LDL, HDL, FBS, HbA1C, INR, PTT, PT, Billirubin (Total, Direct), Albumin, AST, ALT, ALK-P, CRP, the steatosis and hepatic fibrosis patients is measured. Exclusion criteria: Consumption more than 20 gram of alcohol per day for women or more than 30 gram in men for at least 3 consecutive months during five last years; people with hepatitis B,C; chronic liver disease; heart failure; consumer of osteoarthritis medications that cause hepatitis; proven diabetes mellitus; proven hemochromatosis and unwillingness to participate in the project. Intervention: This study will be a pilot study with 120 sample size. Patients enter one of four categories for three months: Intervention group 1: The group that received tabs Melatonin, 10 milligram, one number, daily (Manufacturing factory is Nachermed of America); Intervention group 2: Tab Metformin, 500 milligram, one number, every 12 hours (Manufacturing factory is Aria); Intervention Group 3: Cap Ursodeoxycholic acid, 300 milligram, one number, every 12 hours (Manufacturing factory is Sosefarm of Italia); Control group: Tab Placebo, one number, daily. Diet respected in all groups. At the end of the study, the frequency of existence statuses and fibrosis in patients each group based on the results of Fibro scan and also check liver enzyme levels and other tests will be calculated. Main outcome measures: primary outcome variables are the Body Mass Index and Serum levels of liver enzymes. Also, the secondary

outcome variables are serum lipids and Body Mass Index respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407201155N21**

Registration date: **2015-09-22, 1394/06/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-22, 1394/06/31

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

Guilan University of Medical Sciences,
Gastrointestinal and liver disease Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Gastrointestinal and Liver Disease Research Center

Expected recruitment start date

2015-06-09, 1394/03/19

Expected recruitment end date

2016-03-09, 1394/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Health impact of Melatonin, Metformin and Ursodeoxycholic acid in treatment of patients with Nonalcoholic Fatty Liver Disease (NAFLD)

Public title

Comparison of therapeutic effect of Melatonin, Metformin and Ursodeoxycholic acid with placebo in treatment of patients with Nonalcoholic Fatty Liver Disease (NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Nonalcoholic Fatty Liver Disease (NAFLD) have proven statuses by Fibro Scan.
Exclusion criteria: Consumption more than 20 gram of alcohol per day for women or more than 30 gram in men for at least 3 consecutive months during five last years; patients with hepatitis B, C and other chronic liver diseases including autoimmune liver diseases; patients with heart failure according to the history and clinical signs; patients who take medication causing osteohepatitis such as Tamoxifen, Amiodarone; patients with established diabetes mellitus; patients with established hemochromatosis; dissatisfaction for participate in study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

The randomization in this study is Random Block

Secondary Ids

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics Committee of Gastrointestinal and Liver Disease Research Center of Guilan University of Medic

Street address

Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Sardare Jangal Avenue, Rasht, Guilan province, Iran

City

Rasht

Postal code

4144895655

Approval date

2014-07-09, 1393/04/18

Ethics committee reference number

ش-182

Health conditions studied**1****Description of health condition studied**

Nonalcoholic Fatty Liver Disease (NAFLD)

ICD-10 code

K 76.0

ICD-10 code description

Nonalcoholic Fatty Liver Disease (NAFLD)

Primary outcomes**1****Description**

Serum levels of liver enzymes

Timepoint

initially and three months later

Method of measurement

Laboratory Kit

2**Description**

Steatosis

Timepoint

initially and three months later

Method of measurement

using fibroscan

Secondary outcomes**1****Description**

Serum Lipids

Timepoint

Initially and three months later

Method of measurement

Laboratory Kit

2**Description**

Body Mass Index
Timepoint
Initially and three months later
Method of measurement
with Seca Scale

Intervention groups

1

Description
Intervention group 1: Melatonin, 10 milligram, one number, daily
Category
Treatment - Drugs

2

Description
Intervention group 2: Tab Metformin, 500 milligram one number, every 12 hours
Category
Treatment - Drugs

3

Description
Intervention group 3: Cap Ursodeoxycholic acid, 300 milligram, one number, daily
Category
Treatment - Drugs

4

Description
Control group: Tab Placebo, one number, daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastrointestinal and Liver Diseases Research Center
Full name of responsible person
Farahnaz Joukar
Street address
Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Sardare Jangal Avenue, Rasht, Guilan province, Iran
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Guilan University of

Medical Sciences
Full name of responsible person
Dr Rasool Tabari KHomeirani
Street address
Sadati Street, Namjoo Street, Rasht ,Guilan,Iran
City
Rasht
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 of Guilan University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Behvazan Company
Full name of responsible person
Dr. seyed Mohamad Keshavarz
Street address
Rasht industrialcity Behvazan Company
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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
Behvazan Company
Proportion provided by this source
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
Gastrointestinal and Liver Disease Research Center
Full name of responsible person
Farahnaz Joukar

Position

Assistant of Gastrointestinal and Liver Disease
Research Center

Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****Name of organization / entity**

Gastrointestinal and Liver Disease Research Center

Full name of responsible person

Mehrnaz Asgharnezhad

Position

Researcher of Gastrointestinal and Liver Disease
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Fax**Email****Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dr.Fariborz Mansour-Ghanaei

Position

Professor of internal medicine and gastroenterology
and hepatology

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Web page address**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