Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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
182-ش

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 industrialcirty Behvazan Company

City

Rasht

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

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Assistant of Gastrointestinal and Liver Disease Research Center
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Person responsible for scientific inquiries

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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