Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Compare the therapeutic effect of Melatonin, Metformin and Vitamin E on liver function, sugar and lipid factors in patients with non-alcoholic fatty liver disease (NAFLD) dietary regimen

Protocol summary

Summary

In a clinical trial study, the therapeutic effect of Melatonin, Metformin and Vitamin E in patients with non-alcoholic fatty liver disease (NAFLD) dietary regimen are assessed. Participants were adults with NAFLD diagnosed by increased alanine aminotransferase (ALT), Aspartate Aminotransferase (AST) and liver ultrasound who did not have other liver diseases, including viral (hepatitis B or C), autoimmune hepititis and genetic conditions (hemochromatosis) or other liver disorders. At the first, the weight, height and waist and hip circumferences and biochemical blood serum assessment including blood sugar 2 hours after food (BS 2hpp), gamma-glutamyl transferase (GGT), Ceruloplasmin, Alkaline phosphatase (ALKP), C-reactive protein (CRP), factors of ALT, AST, fasting blood sugar (FBS), hemoglobin A1C, triglyceride (TG), Total Cholesterol, Ferritin are measured. Patients are randomly placed to three groups by sealed envelop method. One group will be received Melatonin tablet (10 mg) once a day for 30 minutes before sleep with their diet regiment for a period of 3 months. The second group will be received Metformin tablet (500 mg) once a day with their diet for a period of 3 months. The third group will be received Vitamin E tablet (800 IU, natural form) once a day with their diet for a period of 3 months. Patients are followed according to the scheduling program for a period of 3 months, and taking the correct medication, side effects, loss of individual samples and unwillingness to continue treatment are examined. After three months of intervention, measuring weight, waist, hip circumferences and biochemical blood serum test are performed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040318124N3**
Registration date: **2017-04-28, 1396/02/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-28, 1396/02/08

Registrant information

Name

Ali Akbar Hajiaghamohammadi

Name of organization / entity

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Compare the therapeutic effect of Melatonin, Metformin and Vitamin E on liver function, sugar and lipid factors in patients with non-alcoholic fatty liver disease (NAFLD) dietary regimen

Public title
The therapeutic effect of Melatonin, Metformin and Vitamin E in patients with non-alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Having non-alcoholic fatty liver disease (NAFLD) without other liver diseases. Exclusion criteria: Alcohol consumption of more than 20 gr per day for women or more than 30 gr in men for at least 3 consecutive months during a recent 5 year period, Patients with autoimmune hepatitis, hepatitis B, hepatitis C and other chronic liver diseases, Patients with heart failure (New York Heart Association class II to IV), Patients taking drugs that cause osteo-hepatitis like fibrates, statins, NSAID, Amiodarone, and Tamoxifen, Patients with proven diabetes mellitus under medical therapy, Patients receiving vitamin C, zinc and selenium or antioxidant agents during a recent three months, Patients with kidney disease and kidney failure or any patients with GFR less than 60.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
Shahid Bahonar Blvd.

City
Qazvin

Postal code

Approval date
2015-12-09, 1394/09/18

Ethics committee reference number
IR.QUMS.REC.1394.218

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease [NAFLD]

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
liver function tests

Timepoint
Before treatment and 3 months later

Method of measurement
blood sample

Secondary outcomes

1

Description
lipid tests

Timepoint
Before treatment and 3 months later

Method of measurement
blood sample

2

Description
sugar tests

Timepoint
Before treatment and 3 months later

Method of measurement
blood sample

Intervention groups

1

Description
Administration of melatonin (10 mg tablet) once a day with diet for a period of 3 months

Category
Treatment - Drugs

2

Description
Administration of metformin (500 mg tablet) once a day with diet for a period of 3 months
Category
Treatment - Drugs

3

Description
Administration of vitamin E (800 IU tablet) once a day with diet for a period of 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Hospital
Full name of responsible person
Dr. Sina Khajeh Jahromi
Street address
Velayat hospital, 22 Bahman Blvd., Taavon square, Minoodar area, Qazvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Qazvin University of Medical Sciences
Full name of responsible person
Dr. Taghi Naserpoor Farivar
Street address
Shahid Bahonar Blvd, Qazvin university of medical sciences
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Qazvin
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, Qazvin University of Medical Sciences
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
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Person responsible for updating data

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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