

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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 hepatitis 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 regimen 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

City

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

Qazvin university of medical sciences

Full name of responsible person

Dr. Sina Khajeh Jahromi

Position

Internal medicine resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Associate Professor

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Person responsible for updating data

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Name of organization / entity

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Position

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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