

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the effects of Melatonin Supplementation on Hepatic Enzymes, Inflammatory Factors, Lipid profile, blood glucose, Insulin Sensitivity, and Hepatic Steatosis grade in patients with Non-alcoholic fatty liver disease

Protocol summary

Summary

Objectives: Nonalcoholic Fatty Liver Disease (NAFLD) is a wide range of clinical symptoms of liver damage that can lead to liver failure. The main cause is the accumulation of fat (triglycerides or TG) in the liver, which promotes inflammation, steatosis and fibrosis progression. Melatonin is considered one of the strongest antioxidants in the body that may improve insulin resistance and dyslipidemia. The main objective of this study is evaluation the effect of Melatonin supplement on blood lipids, liver enzymes, inflammation factors and degree of liver fibrosis in patients with nonalcoholic fatty liver. Design: This study is a double blind randomized clinical trial. Blinding will be imposed on subjects and researchers. Setting and conduct: Patients with NAFLD will be divided in two intervention (receiving Metatonin supplement) and placebo groups. The period of intervention is 12 weeks. Blood samples will be taken before and after of supplementation. Participants (including major eligibility criteria): Inclusion criteria will be age more than 18 years and steatosis degree equal or more than 2 and exclusion criteria will be suffering from other liver diseases, cancer and autoimmune diseases. Intervention: One 5 mg Melatonin capsule per day in intervention group and one placebo capsule per day in placebo group for 12 weeks. Main outcome measures: Levels of lipid profiles, fasting blood glucose and liver enzymes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061516123N8**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Sima Jafarirad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8317

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jafarirad-s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Melatonin Supplementation on Hepatic Enzymes, Inflammatory Factors, Lipid profile, blood glucose, Insulin Sensitivity, and Hepatic Steatosis grade in patients with Non-alcoholic fatty liver disease

Public title

Effects of Melatonin on Non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

A - Inclusion criteria: Age 18 years and older; with evidence of nonalcoholic fatty liver in ultrasonography with a higher degrees and equal 2 of steatosis; the liver enzyme concentration (alanine aminotransferase or ALT) greater than 1.5 times the highest normal. b -exclusion criteria: history of alcohol consumption; chronic and acute liver disorders (hepatitis B, C, ...); biliary diseases; autoimmune diseases; cancer; hereditary disorders affecting on liver condition (storage disease of iron, copper, ...); cardiovascular; pulmonary diseases; kidney diseases; pregnancy; breast-feeding; use of contraceptives; hepatotoxic drugs consumption; use of Mineral- multivitamin supplements; weight loss surgery in the past year; weight loss program in 3 month ago; history of hypothyroidism; Cushing's syndrome.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Iran

City

Ahvaz

Postal code**Approval date**

2016-05-04, 1395/02/15

Ethics committee reference number

IR.AJUMS.REC.1395.155

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

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

nonalcoholic steatohepatitis

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

Alanine transaminase

Timepoint

before intervention and after 3 months

Method of measurement

seum level

2**Description**

Aspartate transaminase

Timepoint

before intervention and after 3 months

Method of measurement

serum level

3**Description**

tumor necrosis factor alpha

Timepoint

before intervention and after 3 months

Method of measurement

serum level

4**Description**

high sensitive C reactive protein

Timepoint

before intervention and after 3 months

Method of measurement

serum level

5**Description**

Triglyceride

Timepoint

before intervention and after 3 months

Method of measurement

serum level

6

Description

Total cholesterol

Timepoint

before intervention and after 3 months

Method of measurement

serum level

7

Description

Low density lipoprotein (LDL)

Timepoint

before intervention and after 3 months

Method of measurement

serum level

8

Description

High density lipoprotein (HDL)

Timepoint

before intervention and after 3 months

Method of measurement

serum level

Secondary outcomes

1

Description

sleep quality

Timepoint

before and 3 months after intervention

Method of measurement

Pittsburgh sleep quality index questionnaire

Intervention groups

1

Description

Melatonin, Tab 5 mg, once a dayT 3 months

Category

Treatment - Other

2

Description

Placebo, 5 mg, 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomieni Hospital

Full name of responsible person

Street address

Emam Khomieni Hospital, Azadegan, Ahvaz, Iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Ahvaz
Jundishapur University of Medical Sciences

Full name of responsible person

Dr.Makhmalzadeh

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan, Ahvaz, Iran

City

Ahvaz

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, Ahvaz
Jundishapur 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sima Jafarirad

Position

Ph.D

Other areas of specialty/work

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Position

Master of Science

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

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185

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