Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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

Email address

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
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Iran
City
Ahvaz
Postal code

Phone
+98 61 3336 7560
Fax
Email
sjafarirad@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Makan cheraghpour
Position
Master of Science
Other areas of specialty/work
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Iran
City
Ahvaz
Postal code
185
Phone
+98 61 3373 8317
Fax
+98 61 3373 8330
Email
bio_makan@yahoo.com
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