Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

The effects of melatonin supplementation compared with placebo on ultrasound findings and metabolic profiles in obese children and adolescents with nonalcoholic fatty liver disease

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of melatonin supplementation on on ultrasound findings and metabolic profiles in obese children and adolescents with nonalcoholic fatty liver disease.

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive melatonin supplement (n=33) or placebo (n=33)

Settings and conduct

Among obese children and adolescents with nonalcoholic fatty liver disease referred to Pediatric Clinic of Shahid Beheshti Hospital affiliated to Kashan University of Medical Sciences, 66 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 16 weeks after the intervention. At the beginning and the end of the intervention: 16 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obese children and adolescents with nonalcoholic fatty liver disease aged 10 to 18 years old. Exclusion criteria: Taking any antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment, patients with infectious and autoimmune diseases, and hypersensitivity to the study medication.

Intervention groups

Intervention group: two melatonin tablets (Simorgh Darou Attar Co., Iran) 6 mg, 3 mg each tablet, once a day, one hour before bedtime for 16 weeks orally. Control group: two Placebo tablets (Simorgh Darou Attar Co., Iran), once a day, one hour before bedtime for 16 weeks orally.

Main outcome variables

Outcomes: hs-CRP (primary outcome) and ultrasound findings, serum liver enzymes, lipid profiles and markers of oxidative damage (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200531047614N2**
Registration date: **2020-11-13, 1399/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-13, 1399/08/23**
Update count: **0**

Registration date

2020-11-13, 1399/08/23

Registrant information

Name

Mohammad Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5554 0026

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rajabi-m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-05, 1399/08/15

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melatonin supplementation compared with placebo on ultrasound findings and metabolic profiles in obese children and adolescents with nonalcoholic fatty liver disease

Public title

Melatonin supplementation in treatment of obese children and adolescents with nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obese children and adolescents diagnosed with nonalcoholic fatty liver. Patients aged 10-18 years old.

Exclusion criteria:

Taking any antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment. Patients with infectious and autoimmune diseases Hypersensitivity to the study medication.

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 66 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients will be randomly assigned into each intervention group by their numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Pediatric clinic of Shahid Beheshti Hospital, affiliated to Kashan University of Medical Science, who is not involved in the trial and not aware of random sequences, will assign the participants to intervention groups. Supplements and placebos are in the same packaging at the Simorgh Darou Attar Pharmaceutical Company. Only the code is written on the packages. Patients, parents and researchers will not know the type of intervention. After analyzing the data, pocket codes will be decoded. Children, their parents, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2020-10-07, 1399/07/16

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.119

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease (NAFLD)

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description
Severity of liver steatosis
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Sonography

2

Description
serum liver enzymes
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
HDL
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Triglycerides
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Glutathione
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: two melatonin tablets (Simorgh Darou Attar Co., Iran) 6 mg, 3 mg each tablet, once a day, one hour before bedtime for 16 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: two Placebo tablets (Simorgh Darou Attar Co., Iran), once a day, one hour before bedtime for 16 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
pediatric Clinic of Shahid Beheshti hospital of Kashan
Full name of responsible person
Dr. Mohammad Reza Sharif
Street address
Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafshe
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Sharif
Position
Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available