

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 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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Email address

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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

Isfahan

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

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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

Subspecialist

Other areas of specialty/work

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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