Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparative investigation of the effect of sour cherry juice (tart cherry) concentrate and Melatonin tablet on improving sleep disorders in children with Attention Deficit Hyperactivity Disorder

Protocol summary

Study aim
Determining the effect of sour cherry concentrate in comparison with Melatonin tables on improving sleep disorder of children between 6 and 12 years old with ADHD

Design
Clinical trial with control and parallel groups, randomized with no blinding

Settings and conduct
This study will be performed on 70 children between 6 and 12 years old referring to Ibn Sina Hospital Psychiatry Clinic. These patients were evaluated using structured interviews and based on DSM-5 diagnostic criteria for attention deficit hyperactivity disorder and sleep disorders. Patients are then randomly divided into two groups of control and intervention with 35 patients in each group. Patients in the control group will be treated with Melatonin tablets every night for 8 weeks. For the same period of time, the intervention group will receive sour cherry concentrate which is equal to the control group in terms of amount of Melatonin. Eight weeks later, patients in both groups will be examined and compared through the the Children's Sleep Habits Questionnaire and Conners' Parent Rating Scale. This study is performed without blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range between 6 and 12 years; ADHD based on DSM-5 criteria; sleep disorder; IQ is within normal range; no obvious organic disease. Exclusion criteria: having any other systemic or psychiatric illness that requires medication; taking medication for treatment of insomnia; taking other psychedelic drugs that affect sleep

Intervention groups
In the control group, melatonin tablets are given every night for 8 weeks. The intervention group receives sour cherry concentrate containing melatonin in a way that the concentration of melatonin received in this group is similar to the control group.

Main outcome variables
Quality of sleep in patients; sleep duration; rate of attention deficit; rate of symptoms of hyperactivity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101130005280N38**
Registration date: **2021-05-18, 1400/02/28**
Registration timing: **prospective**

Last update: **2021-05-18, 1400/02/28**
Update count: **0**

Registration date
2021-05-18, 1400/02/28

Registrant information

Name
Raheleh Nejati

Name of organization / entity
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

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+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-05, 1400/04/14

Expected recruitment end date
2021-10-06, 1400/07/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative investigation of the effect of sour cherry juice (tart cherry) concentrate and Melatonin tablet on improving sleep disorders in children with Attention Deficit Hyperactivity Disorder

Public title
Effect of sour cherry juice concentrate and Melatonin tablet on improving sleep disorders in children with ADHD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range between 6 and 12 years Attention Deficit Hyperactivity Disorder based on DSM-5 criteria Sleep disorder IQ is within normal range No obvious organic disease
Exclusion criteria:
Having any other systemic or psychiatric illness that requires medication Taking medication for treatment of insomnia Taking other psychedelic drugs that affect sleep Addiction to drugs
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization using "random allocation" software will be conducted. In this type of randomization, blocking is usually used to create a balance in the number of samples assigned to each of the studied groups. This study has 17 blocks of 4 and one block of 2. Half of each block belongs to the patients of the control group and the other half belongs to the intervention group.
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 Mashhad University of Medical Sciences
Street address
Daneshgah street, Ghoreishi building
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2019-12-04, 1398/09/13
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.699

Health conditions studied

1

Description of health condition studied
Attention-deficit hyperactivity disorders
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
Quality of sleep in patients
Timepoint
At the beginning of the study and 8 weeks after taking medication
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

2

Description
Sleep duration
Timepoint
At the beginning of the study and 8 weeks after taking medication
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

3

Description
Rate of attention deficit

Timepoint
At the beginning of the study and 8 weeks after taking medication
Method of measurement
Conners' Parent Rating Scale

4

Description
Rate of symptoms of hyperactivity
Timepoint
At the beginning of the study and 8 weeks after taking medication
Method of measurement
Conners' Parent Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In this group, patients are given Melatonin tablets (maximum dose of 3 mg) every night for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in this group receive cherry concentrate containing melatonin every night for 8 weeks. The amount of sour cherry juice concentrate consumption in the intervention group is adjusted so that the amount of melatonin intake is exactly the same as the control group (standardization based on active ingredient). Sour cherry juice will be purchased from Khoosheh Sorkh Shargh Company which is one of the reputable companies in the field of concentrate production.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Child Psychaitry clinic at Ibn-e-Sina hospital
Full name of responsible person
Fatemeh Moharrari
Street address
Ibn-e-Sina psychiatric Hospital, Horre ameli avenue, Boo Ali square
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moharrerif1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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9177899191
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Fatemeh Moharari
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after patients are made unidentifiable.

When the data will become available and for how long
Data can be accessible 6 months after results are published.

To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used
Carrying out analysis on data is permitted.

From where data/document is obtainable
Data can be accessible through an email to the corresponding author.

What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.

Comments