

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 tablets 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)

Phone

+98 51 3711 2540

Email address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9195983134

Phone

+98 51 3711 2721

Email

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

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

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,
Boo Ali square

City

Mashhad

Province

Razavi Khorasan

Postal code

9195983134

Phone

+98 51 3711 2721

Fax

+98 51 3712 4184

Email

mohararif1@mums.ac.ir

Web page address

Person responsible for scientific 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

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,
Boo Ali square

City

Mashhad

Province

Razavi Khorasan

Postal code

9195983134

Phone

+98 51 3711 2721

Fax

+98 51 3712 4184

Email

mohararif1@mums.ac.ir

Web page address

Person responsible for updating data

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

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,
Boo Ali square

City

Mashhad

Province

Razavi Khorasan

Postal code

9195983134

Phone

+98 51 3711 2721

Fax

+98 51 3712 4184

Email

mohararif1@mums.ac.ir

Web page address

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