

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of Melatonin and Agomelatin on sleep problem in children and adolescent with Autism spectrum disorder

Protocol summary

Study aim

Evaluation effect of Agomelatine on sleep disorders in children and adolescents with ASD and comparing the results with Melatonin.

Design

Pts 3-18 with ASD and CSHQscore above 41: the intervention group:Agomelatine 25 mg HS, control group:Melatonin 3 ml for 3-6 1/2 tab and for 6-12 and one tab and for 12-18, 5 mg tab (1)HS, half hour before bed. study is a double blind clinical trial. Randomization in the form of permuted block randomization in blocks based on the sample size in sizes 2, 4, 6, 8 with a ratio of 1:1 in one or two groups, until the sample size is exhausted using the website <https://icostatistics.shinyapps.io/randlist/> will do. Sample size: Taking into the total sleep time, based on the reference, that before the treatment was 449 minutes and after the treatment was 532 minutes, with a standard deviation of 121, a power of 80% and an error of 5%, two groups of 35 pt plus 5, to avoid falling into each group

Settings and conduct

Pt in psychiatric clinics (3-18 ys old) in Imam Hossein Hospital with autism and sleep dis selectet and after informed consent, complete demographic questionnaire, CSHQ (scores above 41), GARS (for autism severity) and KSADS (for R/O comorbid disorder) so treatment starts for 1 month. At the end of 1 month CSHQ will be complete. parents, patient and psychiatrist that completing questionnaires (in both groups) will be blinded, and drugs will be delivered by clinic secretary, under hygienic conditions, in an anonymous and same packages.

Participants/Inclusion and exclusion criteria

CSHQ scor above 41 without sleep apnea and Seizure without ADHD, Dep, Anx Dont use sedative and immunosupressive drugs LFT below 3 times normal without HTN

Intervention groups

Group1 tab Agomelatine 25 mg, group2 tab Melatonin 3mg for under 12 and Melatonin 5mg for above 12yrs on sleep dis in children and adolescents with ASD

Main outcome variables

Improve the score of CSHQ

General information

Reason for update

Acronym

ملاتونین بر خواب اوتیسم

IRCT registration information

IRCT registration number: **IRCT20230607058407N1**

Registration date: **2023-10-30, 1402/08/08**

Registration timing: **retrospective**

Last update: **2023-10-30, 1402/08/08**

Update count: **0**

Registration date

2023-10-30, 1402/08/08

Registrant information

Name

Nezhla Mostafeenezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

dr.nejla.mostafeenezhad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-11, 1402/04/20

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Melatonin and Agomelatin on sleep problem in children and adolescent with Autism spectrum disorder

Public title

Evaluation of the effect of Melatonin and Agomelatin on sleep problem in children and adolescent with Autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

children and adolescents with autism spectrum disorder and with sleep disorders

Exclusion criteria:

doubt to sleep apnea resistant patients

Age

From **3 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: All eligible subjects will be randomly assigned to one of the two groups receiving melathionine and agomelatine with a ratio of 1:1. The randomization method will be permuted block randomization, which blocks will be done based on the sample size in sizes 2, 4, 6, 8 until the sample size is exhausted using the website <https://icostatistics.shinyapps.io/randlist/>. Patients will be included in each group based on the determined sample size and based on the list of randomized individuals (along with a specific research code for each individual)

Blinding (investigator's opinion)

Double blinded

Blinding description

In compliance with health principles, the melatonin and agomelatonin tablets will be removed from the original drug envelope by the clinic secretary and will be given to the parents in the nameless envelope according to the randomization table. With this method, the patient, parent, researcher and statistician do not know the type

of medicine used by each patient.

Placebo

Not used

Assignment

Parallel

Other design features

ASD severity will assessed and depression ,anxiety and ADHD will R/O.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti university of medical science, Medical school, Velenjak, Koodakyar Avn, Daneshjoo Avn, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-06-03, 1402/03/13

Ethics committee reference number

IR.SBMU.MSP.REC.1402.086

Health conditions studied**1****Description of health condition studied**

Autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

2**Description of health condition studied**

sleep disorder

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes**1****Description**

change the score of children sleep habits questionnaire

Timepoint

at the beginning and 1 month later

Method of measurement

children sleep habits questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: slow-release melatonin tab: half a tablet of 3 mg for the age of 3-5 years, one tablet of 3 mg for the age of 6-12, and melatonin 5mg for the age of 12-18, half an hour before bedtime

Category

Treatment - Drugs

2**Description**

Intervention group: Agumelatine tab immediate release 25 mg ,one tablet at night ,half an hour before sleep

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imamhosein hospital

Full name of responsible person

Katayon Razjouyan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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Grant name

no

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nezhla Mostafeenezhad

Position

Specialist Assistant

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

Title and more details about the data/document

The results of the data analysis will be published in the form of an article

When the data will become available and for how long

After publication in domestic or foreign magazines

To whom data/document is available

no body

Under which criteria data/document could be used

From where data/document is obtainable

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What processes are involved for a request to access data/document

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Comments