

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of clonidine and melatonin for treating insomnia in children 6 to 12 years old with anxiety disorder

Protocol summary

Study aim

1. Comparison of the effects of clonidine and melatonin in the treatment of insomnia in 6 to 12 years old children with anxiety disorders
2. Determination of the effectiveness of clonidine in comparison with placebo, at zero, 4 weeks and 6 weeks after the start of the intervention in the treatment of insomnia in 6 to 12 years old children with anxiety disorder
3. Determining the effectiveness of melatonin in comparison with placebo, at zero, 4 weeks and 6 weeks after the start of the intervention in the treatment of insomnia in 6 to 12 years old children with anxiety disorders
4. Comparison of the effectiveness of clonidine and melatonin at zero, 4 weeks and 6 weeks after the start of the intervention in the treatment of insomnia in 6 to 12 years old children with anxiety disorders

Design

randomized clinical trial with group control double blinded randomized with excel sample size: 72

Settings and conduct

double blinded sleep disorder due to anxiety disorder
sina hospital
Coding of the intervention groups was done by one of the clinic's experts who is not part of the planning process, and the research group will be unaware of the coding until the end of the research.

Participants/Inclusion and exclusion criteria

inclusive criteria: Parents' consent for participating in the study
6 to 12 years old
Suffering from one of the types of anxiety disorders
Exclusion criteria: severe adverse effects
Physical illness

Intervention groups

intervention group 1 : 24 children with 6 to 12 years old with insomnia due to anxiety disorders, melatonin, CSHQ
intervention group 2 : 24 children with 6 to 12 years old with insomnia due to anxiety disorders, clonidine , CSHQ
control group: 24 children with 6 to 12 years old with insomnia due to anxiety disorders, placebo , CSHQ

Main outcome variables

Sleep quality of children with anxiety disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220820055756N1**

Registration date: **2022-10-16, 1401/07/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-16, 1401/07/24**

Update count: **0**

Registration date

2022-10-16, 1401/07/24

Registrant information

Name

Ali Jalalifiroozkoohi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3822 9765

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clonidine and melatonin for treating insomnia in children 6 to12 years old with anxiety disorder	
Public title	Comparison of clonidine and melatonin for treating insomnia in children 6 to12 years old with anxiety disorders
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: parent consent for participating in study 6 to12 years old children suffering from atleast one of the anxiety disorders sleep disorder due to anxiety disorders Exclusion criteria: parents dissatisfaction with participating suffering from physical disease using other sedative and hypnotic drugs except clonidine and melatonin history of allergy to clonidine and melatonin
Age	From 6 years old to 12 years old
Gender	Both
Phase	2-3
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser • Data and Safety Monitoring Board
Sample size	Target sample size: 72
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization method: In this study, volunteers will be assigned to three groups by simple randomization method.
Blinding (investigator's opinion)	Double blinded
Blinding description	This study will be conducted in a double-blind manner. The drugs used will be delivered to the mentioned patients in a similar form and appearance. Coding of the intervention groups was done by one of the clinic's experts, who is not part of the research program , and the research group will not be aware of the coding until the end of the research.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethnic committee of Hamedan University of Medical Sciences
Street address	Sina Hospital Mirzade Eshghi Street
City	Hamedan
Province	Hamadan
Postal code	4874165168
Approval date	2022-08-21, 1401/05/30
Ethics committee reference number	IR.UMSHA.REC.1401.460
Health conditions studied	
<u>1</u>	
Description of health condition studied	sleep disorder
ICD-10 code	F51
ICD-10 code description	Sleep disorders not due to a substance or known physiological condition
Primary outcomes	
<u>1</u>	
Description	quality of sleep
Timepoint	week4 and 6
Method of measurement	children's sleep questionnaire
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group:24 children between 6 to 12 years old with sleep disorders due to anxiety disorders who will be treated with melatonin (3 mg). For first three day melatonin will be administrated by 1/4 of a pill .after these days it will be increased to 1/2 of a pill . After one week the mentioned drug will be increased to a pill .It should be noted that after 4 and 6 week the quality of sleep willll be measured by CSHQ.
Category	

Treatment - Drugs

2

Description

Intervention group: 24 children between 6 to 12 years old with sleep disorders due to anxiety disorders who will be treated with clonidine (0.2 mg). For first three days clonidine will be administered by 1/4 of a pill. After these days it will be increased to 1/2 of a pill. After one week the mentioned drug will be increased to a pill. It should be noted that after 4 and 6 weeks the quality of sleep will be measured by CSHQ.

Category

Treatment - Drugs

3

Description

Control group: 24 children between 6 to 12 years old with sleep disorders due to anxiety disorders who will be treated with placebo. For first three days placebo will be administered by 1/4 of a pill. After these days it will be increased to 1/2 of a pill. After one week the placebo will be increased to a pill. It should be noted that after 4 and 6 weeks the quality of sleep will be measured by CSHQ.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Farschian (Sina) Hospital

Full name of responsible person

Dr Helen Behmanesh

Street address

Mirzade Eshghi Street

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a.jalalifiroozkoohi@edu.umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Reza Shokouhi

Street address

4th floor, Setad building, Hamedan Medical

University, Shahid Fahmide Street, Pajohesh Square

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Helen Behmanesh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Helen Behmanesh

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

because the information is collected confidentially from the patients and the information is generally valuable.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

quality of sleep during the use of mentioned drug

When the data will become available and for how long

6 month after publishing

To whom data/document is available

all researcher

Under which criteria data/document could be used

after finishing the project it will publish as an article

From where data/document is obtainable

dr helen behmanesh

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

after finishing the project it will publish as an article

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Ali Jallali Firouzkoohi

Position

resident of psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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