Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The study of effectiveness of melatonin on sleep disorders in children with cerebral palsy (CP)

Protocol summary

Study aim

The effect of melatonin on sleep disorders in children with any type of cerebral palsy

Design

Clinical trial with a control group, with parallel groups, triple blind, randomized, phase 2 on 50 patients. Random blocks with sealed envelopes were used for randomization

Settings and conduct

Children 2 to 12 years old with cerebral palsy who complained of sleep disorders were selected by the convenient sampling method. The study sample size was 50 children. in the intervention group, patients 30 minutes before sleeping received 3 mg melatonin and the control group received placebo (3 mg lactose). The duration of treatment was one month. In both groups in the first two nights, the quality (The time required to fall asleep and the duration of sleep) and depth of sleep without medication was measured. After the second night onwards, both groups received medication and then the quality and depth of sleep at the end of the month in both groups were compared with the first two nights.

Participants/Inclusion and exclusion criteria

Children (boys and girls) 2 to 12 years old with cerebral palsy of any kind who complained of sleep disorders referred to the pediatric neurology clinic of Ghaem Educational, Research and Treatment Center in the holy city of Mashhad. Outcome criteria of this study include non-cooperation of the patient or their parents from participating in the project and the existence of side effects of melatonin during treatment

Intervention groups

In the intervention group, patients received 3 mg oral melatonin tablets 30 minutes before going to bed, and in the control group, patients received a placebo (3 mg oral lactose) 30 minutes before going to bed with the same color, smell, taste, and shape.

Main outcome variables

the quality of sleep (time to fall asleep, duration of sleep, depth of sleep)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191017045142N1**
Registration date: **2021-07-07, 1400/04/16**
Registration timing: **retrospective**

Last update: **2021-07-07, 1400/04/16**
Update count: **0**

Registration date

2021-07-07, 1400/04/16

Registrant information

Name

Hamid Reza Goldouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3846 2224

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The study of effectiveness of melatonin on sleep disorders in children with cerebral palsy (CP)

Public title
The effect of melatonin on sleep disorders in children with cerebral palsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children with cerebral palsy with sleep disorders

Exclusion criteria:
Change in medication which can affect sleep in the past month such as anticonvulsants and sedatives

Age
From **2 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

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 5 blocks of 10. Half of each block belongs to the patients of the control group and the other half belongs to the intervention group. Random sequences created by the software are written on cards and placed in sealed envelopes, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants are not aware of the type of treatment and the intervention. Also, outcome assessors are unaware of the the grouping. Patients in the control group receive placebo drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Organizational Ethics Committee of Mashhad University of Medical Sciences

Street address
Daneshgah street, Ghoreishi building

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2020-01-08, 1398/10/18

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.679

Health conditions studied

1

Description of health condition studied
cerebral palsy

ICD-10 code
G80.0

ICD-10 code description
Spastic quadriplegic cerebral palsy

2

Description of health condition studied
Sleep disorders

ICD-10 code
G47

ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
Time required to start sleep

Timepoint
In both groups, two nights before beginning the study and receiving medication and also at the end of the month after receiving the medicationwith the first two nights (without medication)

Method of measurement
Using the actigraphy method with Xiaomi (China) smart watches which work based on the frequency of hand movement

2

Description
Duration of sleep

Timepoint

In both groups, two nights before beginning the study and receiving medication and also at the end of the month after receiving the medication

Method of measurement

Using the actigraphy method with Xiaomi (China) smart watches which work based on the frequency of hand movement

3

Description

Duration of deep sleep

Timepoint

In both groups, two nights before beginning the study and receiving medication and also at the end of the month after receiving the medication

Method of measurement

Using the actigraphy method with Xiaomi (China) smart watches which work based on the frequency of hand movement

4

Description

Duration of light sleep

Timepoint

In both groups, two nights before beginning the study and receiving medication and also at the end of the month after receiving the medication

Method of measurement

Using the actigraphy method with Xiaomi (China) smart watches which work based on the frequency of hand movement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receive 3 mg oral melatonin tablets produced by (Razak company) 30 minutes before going to sleep. Next, the patient wears a smart watch which, based on the frequency of hand movement, records the time of falling asleep, light and deep sleep and waking up time.

Category

Treatment - Drugs

2

Description

Control group: Patients receive a placebo (3 mg oral lactose) 30 minutes before bedtime with the same color, smell, taste and shape as the medication in the intervention group. Next, the patient wears a smart watch which, based on the frequency of hand movement, records the time of falling asleep, light and deep sleep and waking up time.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Educational, Research and Treatment Center in Mashhad

Full name of responsible person

Hamid Reza Goldouzi

Street address

Ahmad Abad Ave, Ghaem hospial

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research, Mashhad University of Medical Sciences

Street address

Mashhad, University Street, next to Hoveyzeh Cinema, Ghorashi Building, Deputy of Research and Technology

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Email

vcresraech@mums.ac.ir

Web page address

https://v-research.mums.ac.ir/

Grant name

Grant code / Reference number

970653

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

Hamid Reza Goldouzi

Position

Medical sciences pediatrician

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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