# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jul 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**
hamid.reza.goldozian@gmail.com

**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

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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

**City**

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**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 3841 1538

**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

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## Person responsible for scientific inquiries

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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