Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of melatonin on pediateric drug resistant epilepcy

Protocol summary

Summary

In this pilot crossover study, the investigators examined the effect of melatonin on seizures, sleep quality, and behavior in 20 patients. Children with drug-resistant epilepsy, who had referred to epileptic clinic of Qaem hospital, were randomly assigned to receive treatment with melatonin or placebo for 4 weeks and after the washout period; patients who started with melatonin were switched to placebo. Melatonin was administered 30 minutes before bedtime in dose of 0.3 mg /kg of 3 mg tablets. Inclusion criteria: age in pediatrics' range between 1 to 15 years old; failure of at least 3 different antiepileptic drugs to control seizures; therapeutic stability for at least 1 month prior to the study, and 4 seizures or more in the last month prior to the initiation of the study. Exclusion criteria: history of neurodegenerative disorders syndromes, cardiovascular anomalies, liver and kidney dysfunction; history of pseudo seizures, seizures with so large numbers and variety that were uncountable; history of status or progressive seizure attack. Study outcomes: seizures duration, sleep quality, and behavior.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100730187N1**
Registration date: **2016-10-22, 1395/08/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-22, 1395/08/01

Registrant information

Name

Saeedeh Talebi

Name of organization / entity

Pediateric ward, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3845 5241

Email address

talebis2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2012-03-10, 1390/12/20

Expected recruitment end date

2012-11-10, 1391/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on pediateric drug resistant epilepcy

Public title

The effect of melatonin on pediateric drug resistant epilepcy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age in pediatrics' range between 1 to 15 years old; failure of at least 3 different antiepileptic drugs to control seizures; therapeutic stability for at least 1 month prior to the study, and 4 seizures or more in the last month prior to the initiation of the study. Exclusion criteria: history of neurodegenerative disorders syndromes, cardiovascular anomalies, liver and kidney dysfunction; history of pseudo seizures, seizures with so

large numbers and variety that were uncountable; history of status or progressive seizure attack.

Age
From **1 year** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Qureshi Building, Mashhad University of Medical Sciences, Daneshgah St.

City
Mashhad

Postal code

Approval date
2012-02-08, 1390/11/19

Ethics committee reference number
900519

Health conditions studied

1

Description of health condition studied
Intractable epilepsy

ICD-10 code
G40

ICD-10 code description
Epilepsy

Primary outcomes

1

Description
parents’ satisfaction from drug

Timepoint
2 sets of each 4 week

Method of measurement
spicial forms that complete with parents

2

Description
Parents' satisfaction from Sleep

Timepoint
2 sets of each 4 week

Method of measurement
spicial forms that complete with parents

3

Description
Seizures frequency

Timepoint
2 sets of each 4 week

Method of measurement
spicial forms that complete with parents

4

Description
duration of every seizure

Timepoint
2 sets of each 4 week

Method of measurement
spicial forms that complete with parents

Secondary outcomes

1

Description
plasma melatonin level

Timepoint
brfore and after melatonin administration

Method of measurement
blood sample

2

Description
plasma levels of antiepileptic drugs

Timepoint
before and after melatonin administration

Method of measurement
blood sample

3

Description
side effects

Timepoint
During the study within 8 weeks

Method of measurement

question from parants

Intervention groups

1

Description
Intervention group: Melatonin at a rate of 10 mg /m2 was given 30 minutes before bedtime and then after 24 hours placebo administered.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital, pediatric neurology clinic
Full name of responsible person
Dr. Gavad Akhondian, Professor of Pediatric Neurology
Street address
Ghaem hospital, Ahmad Abad St.
City
Masshad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Saeed Eslami
Street address
Qureshi Building, Mashhad University of Medical Sciences, Daneshgah St.
City
Mashhad
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Saeedeh Talebi
Position
Pediatrician
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact
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Full name of responsible person
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quaem.medical.center@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty