

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The effect of melatonin on pediatric drug resistant epilepsy

#### 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

Pediatric 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 pediatric drug resistant epilepsy

##### Public title

The effect of melatonin on pediatric drug resistant epilepsy

##### 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

spical forms that complete with parents

### 2

#### Description

Parents' satisfaction from Sleep

#### Timepoint

2 sets of each 4 week

#### Method of measurement

spical forms that complete with parents

### 3

#### Description

Seizures frequency

#### Timepoint

2 sets of each 4 week

#### Method of measurement

spical forms that complete with parents

### 4

#### Description

duration of every seizure

#### Timepoint

2 sets of each 4 week

#### Method of measurement

spical 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 parents

## 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

Mashhad

## 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

#### Street address

Ghaem hospital, Ahmad Abad St.

#### City

Mashhad

#### Postal code

#### Phone

+98 51 3840 0001

#### Fax

#### Email

talebis2@mums.ac.ir;

quaem.medical.center@mums.ac.ir

#### Web page address

quaem.mums.ac.ir

## Person responsible for scientific 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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quaem.medical.center@mums.ac.ir

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Saeedeh Talebi

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Pediatrician

#### Other areas of specialty/work

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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*