Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of the effect of melatonin on children with refractory seizure

Protocol summary

Study aim

The aim of this study was to compare the frequency of seizures, duration of seizures, possible complications, improvement of behavioral disorder and sleep cycle disorder before and after treatment with melatonin and placebo in intervention and control groups

Design

The study design is clinical trial with a control group, with parallel groups, single blind and simple randomization and patients will be studied in two groups of 25 cases.

Settings and conduct

In this clinical trial, children referred to the pediatric neurology clinic of BouAli Hospital in Sari are examined. Patients are blind and will be evaluated by simple random sampling

Participants/Inclusion and exclusion criteria

Children from 1 to 21 years with seizures who have not been controlled with at least three different antidepressants and who have had at least four or more seizures a month before the study are included. Exclusion criteria are unrepeatable seizures, history of cardiovascular and neurodegenerative syndromes, liver and kidney dysfunction, history of pseudo seizures, blindness, lack of compliance (irregular drug use, unreliable parenting, severe and persistent progressive seizures), and a history of vasculitis.

Intervention groups

The intervention group will be prescribed melatonin tablet at a dose of 10 mg/m2 body surface area in the form of a 3 mg tablet manufactured by Razak Pharmaceuticals. In the control group, placebo with the combination of tricalcium phosphate, magnesium stenarate and starch adhesive is also given with a similar shape, color and taste. Patients will take the pills daily and one hour before bedtime (along with their anticonvulsants) for 4 weeks.

Main outcome variables

The main outcomes of the study are treatment response rate including seizure frequency, duration of seizure, possible complications, improvement of behavioral disorder and sleep cycle disorder before and after the treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090412001808N6**
Registration date: **2019-12-03, 1398/09/12**
Registration timing: **retrospective**

Last update: **2019-12-03, 1398/09/12**
Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name
Ali Abbaskhanian

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 15 1223 3010

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-15, 1398/01/26

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2019-09-22, 1398/06/31

Trial completion date

2019-11-21, 1398/08/30

Scientific title
Clinical trial of the effect of melatonin on children with refractory seizure

Public title
Effect of melatonin on refractory seizure of children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 1 to 21 years with a history of seizure Seizure is not controlled with at least 3 different anticonvulsants At least four or more seizure episodes in last month
Exclusion criteria:
Treatable seizure History of cardiovascular syndromes Neurodegenerative syndromes Hepatic and renal dysfunction History of pseudo seizure Blindness Irregular drug use Unreliable parents History of vasculitis Severe and persistent progressive seizure
Age
From **1 year** old to **21 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4. Randomization will be done using the software randomization option in Excel. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process.
Blinding (investigator's opinion)
Single blinded
Blinding description
Since the placebo capsule has the same shape, color, and taste of the intervention drug, the patient is blind and unaware of the drug being used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2019-07-02, 1398/04/11
Ethics committee reference number
IR.MAZUMS.REC.1398.633

Health conditions studied

1

Description of health condition studied
Refractory seizure
ICD-10 code
G40
ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
Frequency and duration of seizure
Timepoint
Baseline (before intervention), first, second, third and fourth weeks
Method of measurement
Frequency and duration of seizure in day

2

Description
Sleep quality
Timepoint
Baseline (before intervention), first, second, third and fourth weeks
Method of measurement
The Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be prescribed melatonin tablet at a dose of 10 mg/m2 body surface area in the form of a 3 mg tablet manufactured by Razak Pharmaceuticals. Patients will take the pills daily and one hour before bedtime (along with their anticonvulsants) for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: In the control group, placebo with combination of tricalcium phosphate, magnesium stenarate and starch adhesive made by Razak Pharmaceuticals is also given with a similar shape, color and taste. Patients will take the pills daily and one hour before bedtime (along with their anticonvulsants) for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Neurology clinic of Bouali hospital of Sari

Full name of responsible person

Dr. Ali Abbaskhanian

Street address

Bouali Hospital, Pasdaran Boulevard, Sari, Iran

City

Sari

Province

Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeidi, Vice chancellor for research, Mazandaran University of Medical Sciences

Street address

Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem square, Sari

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ali Abbaskhanian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

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Dr. Ali Abbaskhanian

Position

Associate professor

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Person responsible for updating data

Contact
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Full name of responsible person
Dr. Atena Amirkhanloo
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not 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
Part of the data is shareable after people are unrecognizable
When the data will become available and for how long
starting from April 2020
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Anyone
From where data/document is obtainable
Call Dr. Ali Abbaskhanian, Email: snali45@yahoo.com
What processes are involved for a request to access data/document
Send email
Comments