Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of melatonin plus propranolol and propranolol on the improvement of symptoms of migraine headache with sleep disorders in children

Protocol summary

Study aim
Comparison of the effects of melatonin plus propranolol and propranolol alone on the improvement of migraine and sleep disorders in children referred to the neurology clinic of Besat Hospital in 1398

Design
Parallel

Settings and conduct
In this study, children aged 5 to 15 years old admitted to the pediatric neurology clinic of Besat Hospital of Hamedan with a headache complaint that diagnosed migraines based on the classical and international prevalence of migraine criteria (Appendix No. 1) and repeated attacks with the following conditions: Will be enrolled.Also, sleep disorders based on the CSHQ Questionnaire (Appendix 2) should be established in these patients. Monitoring of patients during the first month of treatment and in patients who continue their treatment with PEDMIDAS (Appendix 3) at the end of the first three months. Satisfaction with treatment is assessed

Participants/Inclusion and exclusion criteria
1- Children aged 5 to 15 years 2. A definitive diagnosis of migraine disease by a neurologist. 3- Rejection of other causes of headache 4. Family consent to attend the project

Intervention groups
Consumption of propranolol with melatonin and propranolol alone

Main outcome variables
Migraine and sleep disorders

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190619043946N1**
Registration date: **2020-03-09, 1398/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-09, 1398/12/19**
Update count: **0**

Registration date
2020-03-09, 1398/12/19

Registrant information

Name
Abbasali Abdollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3264 0020

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abbasali.abdollahi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of melatonin plus propranolol and propranolol on the improvement of symptoms of migraine headache with sleep disorders in children

Public title
Comparison the effect of melatonin plus propranolol and propranolol on the improvement of symptoms of migraine headache with sleep disorders in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- Children aged 5 to 15 years 2. A definitive diagnosis of migraine disease by a neurologist. 3- Rejection of other causes of headache 4. Family consent to attend the project 5. Suitable for the onset of migraine prophylaxis: more than one attack per week, more than a disabling attack (leading to school absenteeism or dysfunction, PEDMIDAS of more than 20 6. Sleep disturbance includes: late sleep, early waking, low sleep, frequent waking up during nighttime sleep.
Exclusion criteria:
1-For any reason, patients tend to continue to study or change the diagnosis. 2- Cases of other underlying illnesses that do not have the ability to use propranolol.
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
The quadruple block method is used for randomization in this trial. How to randomize is AABB, ABAB, BABA, BBAA,. The randomization unit is individual. Codes are assigned to the samples for concealment.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee for Biomedical Research
Street address
Tehran-Ghods Town (West) - Between South Falamak and Zarafshan, Iran's Sims Avenue-Headquarters of the Ministry of Health and Medical Education, block A, thirteenth floor
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2019-06-18, 1398/03/28
Ethics committee reference number
IR.UMSHA.REC.1398.236

Health conditions studied

1

Description of health condition studied
Migraine and sleep disorders
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Migraine
Timepoint
Patients are evaluated 1 month after treatment and in those who continue to receive treatment at the end of the first three months the rate of recovery is assessed.
Method of measurement
The severity of migraine headaches is assessed using the PEDMIDAS method.

2

Description
sleep disorders
Timepoint
Patients are evaluated 1 month after treatment and in those who continue to receive treatment at the end of the first three months the rate of recovery is assessed.
Method of measurement
Child Sleep Disorder will be assessed using the CSHQ Child Sleep Habits Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Consumption of propranolol with dosage 1 mg / kg divided into 2 doses Along One tablet of melatonin 3 mg daily for three months
Category

Treatment - Drugs

2

Description
Control group: Consumption of propranolol alone with dosage 1 mg / kg divided into 2 doses for three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Abbas Ali Abdollahi
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Hamedan-Fatemi Blvd.
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6514845411
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Hamedan facing the people park
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Province
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Postal code
5617865178
Phone
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Email
m_research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Ali Abdollahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available