

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Email address

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

Street address

Hamedan-Fatemi Blvd.

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Postal code

6514845411

Phone

+98 81 3264 0064

Email

abbasali.abdollahi@yahoo.com

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

+98 81 3838 0717

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 scientific 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

Contact

Name of organization / entity

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Full name of responsible person

Abbas Ali Abdollahi

Position

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Latest degree

Medical doctor

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Pediatrics

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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