

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of propranolol with melatonin versus propranolol alone on the clinical symptoms in children with migraine without sleep disorder: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of propranolol with melatonin versus propranolol alone on the clinical symptoms in children with migraine without sleep disorder

Design

This is a randomized clinical trial, phase II, in which 32 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible children with migraines without sleep disorder referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 5 to 15 years, Migraine without sleep disorder. Non-inclusion criteria: Contraindication of propranolol or melatonin

Intervention groups

Intervention group: Propranolol tablet (manufactured by Razak Pharmaceutical Co.) 1 mg/kg daily for 3 months plus melatonin tablet (manufactured by Razak Pharmaceutical Co.) 3 mg daily for 3 months. Control group: Propranolol tablet (manufactured by Razak Pharmaceutical Co.) 1 mg/kg daily for 3 months.

Main outcome variables

The severity of headache, nausea and vomiting, photophobia, phonophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N345**

Registration date: **2020-03-13, 1398/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-13, 1398/12/23**

Update count: **0**

Registration date

2020-03-13, 1398/12/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of propranolol with melatonin versus propranolol alone on the clinical symptoms in children with migraine without sleep disorder: a randomized clinical trial

Public title

Effect of propranolol with melatonin on the clinical

symptoms in children with migraine

IR.UMSHA.REC.1398.517

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 5 to 15 years Migraine without sleep disorder

Exclusion criteria:

Contraindication of propranolol or melatonin

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh avenue

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-09-28, 1398/07/06

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Migraine without sleep disorder

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Severity of headache

Timepoint

Before the intervention and 1 and 3 months after that

Method of measurement

By using Visual Analog Scale (VAS)

2

Description

Nausea and vomiting

Timepoint

Before the intervention and 1 and 3 months after that

Method of measurement

By taking history

3

Description

Photophobia

Timepoint

Before the intervention and 1 and 3 months after that

Method of measurement

By taking history

4

Description

Phonophobia

Timepoint

Before the intervention and 1 and 3 months after that

Method of measurement

By taking history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Propranolol tablet (manufactured by Razak Pharmaceutical Co.) 1 mg/kg daily for 3 months

plus melatonin tablet (manufactured by Razak Pharmaceutical Co.) 3 mg daily for 3 months

Category

Treatment - Drugs

2**Description**

Control group: Propranolol tablet (manufactured by Razak Pharmaceutical Co.) 1 mg/kg daily for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital in Hamadan

Full name of responsible person

Dr Paria Abbasian

Street address

Besat Hospital, Shahed Square

City

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6517838695

Phone

+98 81 3364 0030

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

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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

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

Dr Paria Abbasian

Position

Resident Pediatrics

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

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Position

Podiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available