Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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

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

IR.UMSHA.REC.1398.517

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

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Besat Hospital, Shahed Square

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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

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Position

Podiatrist

Latest degree

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Other areas of specialty/work

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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