

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the effect of vitamin B6 and propranolol on Prevention of relapse of migraine headaches in children aged 7-17 years old referring to the pediatric clinic of Amirkabir Arak Hospital

Protocol summary

Study aim

Comparison of the effect of vitamin B6 and propranolol on Prevention of relapse of migraine headaches in children aged 7-17 years old referring to the pediatric clinic of Amirkabir Arak Hospital

Design

A clinical trial performing on 62 children with migraine headaches aged 7-17 years who referre to the pediatric clinic of Amir Kabir Hospital in Arak. These children will divided into two equal groups of propranolol and vitamin B6.

Settings and conduct

A clinical trial study in which 62 children with migraine headaches aged 7-17 years who referre to the pediatric clinic of Amir Kabir Hospital in Arak will enrole. These children will divided into two groups, Propranolol and Vitamin B6. The propranolol group will receive propranolol orally 10 mg daily for three months and the vitamin B6 group will receive 40 mg oral vitamin B6 daily for three months.

Participants/Inclusion and exclusion criteria

inclusion criteria :Children with migraine headaches at the age of 7-17 years who are allowed to study by their parents. Exclusion criteria : Propranolol contraindications, such as difficulty breathing, or wheezing, palms and feet cold, heart rate below 60 per minute, asthma or emphyzema, congestive heart failure, diabetes, hyperthyroidism, depression Kidney or liver failure Allergy to Vitamin B 6

Intervention groups

group 1 : 31 patients given oral propranolol 10 mg once daily. group 2 : Intervention group: 31 patients given oral vitamin B6 40 mg once daily

Main outcome variables

Duration of Migraine Headache Attacks - The number of migraine headaches a week - The severity of headache disability

General information

Reason for update

- Randomization field: Patients who enter the study will receive one of the first or second treatments according to the decision of the treating physician. - Blinding field: Due to the impossibility of preparing a placebo, the study will not be blinded. - Expected end date of sampling field: Sampling has not started yet and will take several months after starting. - Other fields: Some minor spelling and writing problems.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N2**

Registration date: **2020-01-25, 1398/11/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-08, 1399/11/20**

Update count: **1**

Registration date

2020-01-25, 1398/11/05

Registrant information

Name

Amin Haji seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vitamin B6 and propranolol on Prevention of relapse of migraine headaches in children aged 7-17 years old referring to the pediatric clinic of Amirkabir Arak Hospital

Public title

Comparison of the effect of vitamin B6 and propranolol on Prevention of relapse of migraine headaches in children aged 7-17 years old referring to the pediatric clinic of Amirkabir Arak Hospital

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with migraine headaches at the age of 17-17 years who are allowed to study by their parents.

Exclusion criteria:

Propranolol contraindications, such as difficulty breathing, or wheezing, palms and feet cold, heart rate below 60 per minute, asthma or emphyzema, congestive heart failure, diabetes, hyperthyroidism, depression
Kidney or liver failure Allergy to Vitamin B 6

Age

From **7 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Basij Square, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-09-29, 1398/07/07

Ethics committee reference number

IR.ARAKMU.REC.1398.186

Health conditions studied**1****Description of health condition studied**

migrain

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

Duration of Migraine Headache Attacks

Timepoint

Measured weekly by the patient himself at baseline and three months after taking the medication

Method of measurement

the watch

2**Description**

The number of migraine headaches a week

Timepoint

Measured weekly by the patient himself at baseline and three months after taking the medication

Method of measurement

numbers

3**Description**

The severity of headache disability

Timepoint

Measured weekly by the patient himself at baseline and three months after taking the medication

Method of measurement

with Pediatric Migraine Disability Assessment Score questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

31 patients given oral propranolol 10 mg once daily. The duration of the drug is three months

Category

Treatment - Drugs

2

Description

Intervention group: 31 patients given oral vitamin B6 40 mg once daily. The duration of the drug is three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amir Kabir Hospital

Full name of responsible person

Dr Fakhreddin Shariatmadari

Street address

Vice Chancellor for Education, Amir Kabir Hospital,
Arak, Iran

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shariat.8666@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjmandzadegan

Street address

Vice-Chancellor's Office for Research, Peyambar
a'zam university complex, Sardasht

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arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Ali Motafakker Azad

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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Other areas of specialty/work
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When the article was out of print.

When the data will become available and for how long

After publishing the article

To whom data/document is available

University researchers

Under which criteria data/document could be used

If there are any further questions

From where data/document is obtainable

Dr Fakhreddin Shariatmadari

What processes are involved for a request to access data/document

Letter writing should be done with professors and universities.

Comments