Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 17-17 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 17-17 years who referre to the pediatric clinic of Amir Kabir Hospital in Arak will enrolle. 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 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

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 seyyed 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
City
Arak
Province
Markazi
Postal code
3819691187
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
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
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
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
Street address
Vice Chancellor for Education, Amir kabir Hospital, Arak, Iran
City
Arak
Province
Markazi
Postal code
3819691187
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
ali_m_azad@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person
Dr Fakheriddin Shariatmadari

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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

City
Arak

Province
Markazi

Postal code
3819691187

Phone
+98 86 3222 2003

Fax
+98 86 3222 2003

Email
shariat.8666@yahoo.com

Person responsible for updating data

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

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

City
Arak

Province
Markazi

Postal code
3819691187

Phone
+98 86 3222 2003

Fax
+98 86 3222 2003

Email
ali_m_azad@yahoo.com

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