Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Analysis of probiobitcs effect in pediatric migraine prophylaxis

Protocol summary

Study aim
Analysis of probiobitcs effect in pediatric migraine prophylaxis

Design
A clinical trial with a control group with a parallel-group design, single-blind; randomized; Phase 2-3, on 20 patients. Block randomization method for randomization.

Settings and conduct
In this study, children aged 5 to 15 years old were 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 will be enrolled.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 5 to 15 years; A definitive diagnosis of migraine disease by a neurologist; Family consent to attend the project; Suitable for the onset of migraine prophylaxis: (leading to school absenteeism or dysfunction, PEDMIDAS of more than 20) Exclusion criteria: Other types of headaches including chronic or drug-related headaches; Inflammatory bowel disease; Having neurological disorders; Use of antibiotics for 2 months before the start of the study; Use of probiotic supplements 2 weeks before the start of the study; Prohibition of propranolol in patients such as asthma and diabetes.

Intervention groups
In the intervention group, consumption of propranolol with dosage 1 mg/kg divided into 2 doses along 250 mg Yumogi capsule from Yomogi company for 2 months in the control group only propranolol is given.

Main outcome variables
Primary outcomes include monthly frequency, severity, duration, and a disability score of migraine headache that will be compared before and after two months of treatment. The severity of headache will be assessed by asking each child to grade the majority of headache pain on a 10-point scale as no pain = scale of 0 and the most severe pain = 10. Headaches disability will be assessed by the Pediatric Migraine Disability Assessment score questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160523028008N22**
Registration date: **2022-03-05, 1400/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-05, 1400/12/14**
Update count: **0**

Registration date
2022-03-05, 1400/12/14

Registrant information
Name
Mohammad Faryadras
Name of organization / entity
Hamadan University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-02-20, 1400/12/01
Expected recruitment end date
2022-04-19, 1401/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Analysis of probiobitcs effect in pediatric migraine prophylaxis

Public title
Probiobitcs effect in pediatric migraine
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 5 to 15 years A definitive diagnosis of migraine disease by a neurologist Family consent to attend the project Suitable for the onset of migraine prophylaxis: (leading to school absenteeism or dysfunction, PEDMIDAS of more than 20)
Exclusion criteria:
Other types of headaches, including chronic or drug-related headaches Inflammatory bowel disease Having neurological disorders Use of antibiotics for 2 months before the start of the study Use of probiotic supplements 2 weeks before the start of the study. Prohibition of propranolol in patients such as asthma and diabetes.
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Investigator

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two groups based on a table of random numbers. Random number table is a set of numbers that are produced without a specific pattern or order and in a completely random manner and become a table. In order to use a random number table, the researcher must first predetermine the table to read the numbers (for example, up, down, left, or right). Individual for the control group). The researcher then touches one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The researcher who had measured and recorded the indices was not aware of the intervention which was performed for patients to conduct single blinding manner.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmide
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2022-02-05, 1400/11/16
Ethics committee reference number
IR.UMSHA.REC.1400.878

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Monthly frequency of headache
Timepoint
Before and two months after treatment
Method of measurement
Asking from patient

2

Description
Severity of headache
Timepoint
Before and two months after treatment
Method of measurement
Asking from patient

3

Description
Pediatric Migraine Disability score

Timepoint
Before and two months after treatment
Method of measurement
Asking from patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Consumption of propranolol (Tolid Daroo, Pharmaceutical) with dosage 1 mg/kg divided into 2 doses along 250 mg Yumogi capsule from Yomogi company for 2 months.
Category
Treatment - Drugs

2

Description
Control group: Consumption of propranolol with dosage 1 mg/kg divided into 2 doses
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Bentolhoda Keshtkar sohi
Street address
Hamedan-Fatemi Blvd.
City
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6514845411
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hodakeshtka86@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza Shokohei
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh
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Email
vc_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
Bentolhoda Keshtkar Sohi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Latest degree
Medical doctor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is not 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