

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The Effect of Vitamine B-complex Supplementation on Serum Homocysteine Level and The Disease Severity in Children with Typical-Migraine

Protocol summary

Study aim

1. Evaluation and comparison of the frequency of migraine attacks and serum homocysteine levels in children with migraine in the vitamin and control groups.
2. Evaluation and comparison of the frequency of migraine attacks and serum homocysteine in children with migraine before and after the vitamin administration.
3. Evaluation and comparison of the frequency of migraine attacks and serum homocysteine levels in children with migraine before and after administration of placebo.
4. Evaluation of correlation between serum homocysteine and frequency of attacks in children with typical migraine in the vitamin and control (placebo) groups.

Design

A double-blind clinical trial with a age, sex, and migraine severity matched control group.

Settings and conduct

The children with migraine referred to Tabriz Children's Hospital will be studied. The patients will be divided into vitamin and control groups (placebo) in such a way that the patients, data collectors and analyzers will be blinded about the grouping.

Participants/Inclusion and exclusion criteria

90 children under the age of 12 years; with a typical migraine; after obtaining informed consent from their parents will enter the study (inclusion criteria). Patients with congenital anomalies; cardiovascular diseases; metabolic diseases will not enter the study (exclusion criteria).

Intervention groups

Patients will be divided into two age, gender and disease severity matched vitamin and control groups, 45 patients per each. Then the patients in vitamin group will receive vitamin B-complex. In the control group, the same amount of placebo (placebo) will be prescribed.

Main outcome variables

1. The serum levels of Homocysteine.
2. The Migraine severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131012014988N6**

Registration date: **2018-12-21, 1397/09/30**

Registration timing: **prospective**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

Registration date

2018-12-21, 1397/09/30

Registrant information

Name

Mohammad Barzegar

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3526 2265

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Vitamine B-complex Supplementation on Serum Homocysteine Level and The Disease Severity in Children with Typical-Migraine

Public title
The effect of Vitamin B-Complex on Migraine

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children under 12 years of age with typical migraine
Obtain informed consent Has at least one migraine attack per week
Exclusion criteria:
Congenital anomalies Cardiovascular diseases Metabolic diseases

Age
To **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **2**
One sample will be taken before the intervention and one sample will be taken after intervention from each person in each study group.

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients, health care personnel (doctors, nurses, etc.), data collectors and data analyzers will not be informed about grouping.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Pediatric Health Research Center, Tabriz Children Hospital, Sheshgelan St.

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Approval date

2018-12-05, 1397/09/14

Ethics committee reference number

IR.TBZMED.REC.1397.544

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine with aura

Primary outcomes

1

Description

Migraine Severity: The frequency of migraine attacks per week.

Timepoint

At the beginning of the study (before intervention), and 8 weeks after the intervention.

Method of measurement

Questionnaire

Secondary outcomes

1

Description

The serum levels of Homocysteine

Timepoint

At the beginning of the study (before intervention), and 8 weeks after the intervention.

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Vitamin B-complex (Vitamix-Razak-Iran) will orally administer to intervention group. Vitamin B complex consists of several vitamins from the family of B vitamins. In this study, the prescription is given in ml, based on the instructions of the company. According to the daily requirement in this study, the dose of 1 ml/kg/day will orally administer to children for 8 weeks.

Category

Lifestyle

2

Description

Control group: a placebo of vitamin B complex (Vitamix-Razak-Iran) will be orally administer to the patients in the control group. In this study, the dose of 1 ml/kg/day will be administered orally to children for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Mohammad Barzegar

Street address

Tabriz Children Hospital, Sheshgelan Street.

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sina_raeisi7007@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

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Research Vice-Chancellor, Tabriz University of Medical Sciences, Daneshgah Street.

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sina Raeisi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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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

Not applicable