

# 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)

##### Phone

+98 41 3526 2265

##### Email address

phrc\_mb@tbzmed.ac.ir

##### 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.

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

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#### Phone

+98 41 3526 2265

#### Fax

+98 41 3526 2265

#### Email

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

#### Street address

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

#### City

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#### Email

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

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## Person responsible for scientific 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 updating data**

**Contact**

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Tabriz University of Medical Sciences

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**Position**

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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