

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of riboflavin to prevent the migraine in 5-13 year-old children

Protocol summary

Summary

Migraine is the most common cause of recurrent headache in children. According to a theory, migraine may be caused by decreased mitochondrial energy store. In this study, we will compare efficacy of high and low dose riboflavin for prophylaxis of migraine in 5-13 year-old children. In first group, 50mg riboflavin twice daily, in second group, 100mg riboflavin twice daily and in third group, placebo(neutral drug) twice daily will be prescribed for 2 months. Patients will be selected randomly in pediatric neurology clinic of Shahid Beheshti hospital and neurologic clinic of Kashan. The medications will be prescribed in all groups by double-blind method. The response will be evaluated during the last month of treatment according to decrease of headache intensity by one degree(severe to moderate or moderate to mild), decrease of headache duration and frequency(monthly attacks) by 50%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020412361N1**

Registration date: **2013-03-09, 1391/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-09, 1391/12/19

Registrant information

Name

Babak Soltani

Name of organization / entity

Kasahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1557 5840

Email address

soltani_b@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-03-01, 1391/12/11

Expected recruitment end date

2014-03-02, 1392/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of riboflavin to prevent the migraine in 5-13 year-old children

Public title

The effect of riboflavin to prevent the migraine in 5-13 year-old children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 5-13 year-old migraineous children according to ICHD II criteria who have minimally two moderate to severe migraine attacks monthly. Exclusion criteria: Epilepsy or severe neurologic disorders ; Liver, kidney, GI, metabolic or cardiovascular disorders ; Use of migraine prophylactic drugs during the last month ; Incooperation of parents or patients ; Headache attacks less than twice per month ; Tension headache ; Mild migraine headache

Age

From **5 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

5th Kilometer Ghotbe Ravandi Bulv , Kashan
University of Medical Sciences

City

Kashan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

9173

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

duration of headache

Timepoint

last month of treatment

Method of measurement

interview with parents and child

2

Description

intensity of headache

Timepoint

last month of treatment

Method of measurement

interview with parents and child

3

Description

frequency of headache attacks

Timepoint

last month of treatment

Method of measurement

interview with parents and child

Secondary outcomes

1

Description

urine color change

Timepoint

during the study weekly

Method of measurement

interview with parents and children

Intervention groups

1

Description

Interventional group1: Riboflavin 50mg BID for 2 months

Category

Prevention

2

Description

Control group: placebo(neutral drug) for 2 months

Category

Prevention

3

Description

Interventional groups2: Riboflavin 100mg BID for 2 months

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Shahid Beheshti Hospital, Kashan,
Iran

Full name of responsible person

Dr. Ahmad Talebian

Street address

Shahid Beheshti Hospital, 5th Kilometer Ghotbe
Ravandi Bulv, Kashan, Iran

City

Kashan

2

Recruitment center

Name of recruitment center

Neurology Clinic of Kashan City, Iran

Full name of responsible person

Dr. Ahmad Talebian

Street address

Number 5 Flat, Number 25, Medical Site, Kamalolmolk
Square, Kashan, Iran

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

Street address

5th Kilometer Ghotbe Ravandi Bulv , Kashan
University of Medical Sciences

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Babak Soltani

Position

Pediatric Infectious Diseases Specialist/Assistant

Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty