Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of Riboflavin and Amitriptyline in Frequency and Intensity of migraine Attack in Patients with Migraine Headache

Protocol summary

Study aim

The effect of riboflavin and amitriptyline on frequency of migraine attacks and intensity of headache, comparing the demographic characteristics, headache indicators, side effects of studied drugs

Design

72 patients with migraine headaches were selected by IHS criteria and availability. The study was conducted in two groups of (36 N) to evaluate the effect of riboflavin (100 mg twice in day) and amitriptyline (single dose of 25 mg) on frequency and intensity of attacks. Both groups are re-evaluated one and three months later for the headache indicators.

Settings and conduct

a single blinded randomized clinical trial (the project researcher measures migraine control indicators) was performed on migraine patients referred to Bu Ali Qazvin Hospital in 2023. The data of both groups (riboflavin and amitriptyline) are analyzed using SPSS 26 software and independent t test, one way ANOVA and chi square

Participants/Inclusion and exclusion criteria

inclusion: Migraine headache according to IHS criteria; Migraine history during the last year; frequency of 2 to 8 times per month; Age between 18 to 65 years old; Rule out other types of headache exclusion: receipting of painkillers more than 15 times a month; received more than 3 prophylaxis trials; pregnancy, taken another prophylaxis medicine for less than a month; drug sensitivity; Patients who stop the medication receipt and follow up

Intervention groups

Intervention in patients with inclusion criteria is performed to investigate the effect of riboflavin(200 mg) and amitriptyline(25 mg) on controlling the number, severity of attacks and other headache indicators. Then the headache indices and drug side effects of both groups are re-evaluated one and three months later

Main outcome variables

reducing the attacks, intensity and duration of headache, presenting the results to hospitals and pharmaceutical companies as an alternative prophylaxis drugs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059240N1**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date

2023-12-18, 1402/09/27

Registrant information

Name

Forough Ebrahimtabar

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2025-09-29, 1404/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Riboflavin and Amitriptyline in Frequency and Intensity of migraine Attack in Patients with Migraine Headache

Public title
Efficacy of Riboflavin and Amitriptyline in Migraine Attack

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Migraine with or without aura based on IHS criteria Migraine history since the last year Migraine with frequency of 2 to 8 times per month or at least 2 days of headache per month Patient's age should be between 18 to 65 years old The migraine headache must be completely distinguished from other types

Exclusion criteria:
Tension headache or other types more than 15 times a month Daily recipient of painkillers more than 15 times a month Patients who received more than 3 complete prophylaxis trials and did not respond to prophylactical treatment Pregnancy or planning for pregnancy Taken another prophylaxis medicine for less than a month Drug abruptions (drug reaction) Patients who don't want to continue the treatment or stop the medication receipt Patients who referred not for further evaluation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Investigator

Sample size
Target sample size: **36**
More than 1 sample in each individual
Number of samples in each individual: **36**
The patients of the first group (A): has administrated riboflavin at a dose of 100 mg twice a day in 36 patients and the second group (B): Amitriptyline has administered at a dose of 25 mg per day in 36 patients

Randomization (investigator's opinion)
Randomized

Randomization description
Based on random allocation, these patients are divided into two groups: amitriptyline and riboflavin (200 mg). Patients are divided in to two treatment groups A and B using the method of random blocks (Balance block randomization), the size of each block is 6 and the total number of blocks is 12. Blocking is usually used in order to balance the number of samples allocated to each of the studied groups. This feature helps researchers to ensure that the number of samples assigned to each of the study groups is equal in cases. Blocking is carried out in two ways. In the first method, the size of all the blocks is equal (for example, in a two-group experiment, blocks of 8 including 4 participants in the intervention group and 4 participants in the control group) and in the second method, the size of the blocks is randomly selected (for example, blocks 6, 8, 10 and 14 which are available in each block in equal numbers from each group). The method of allocation of balanced randomization for the participants in the randomized controlled clinical trial study is the effect of riboflavin with a dose of 200 mg (group A) and amitriptyline with a dose of 25 mg (group B) to evaluate the frequency and severity of attacks.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study was designed as a single blind. Participants have completely informed about the implementation of the study, the duration of follow-up, the drugs, and the side effects and advantages of the studied drugs, as well as the studies conducted in this field by someone from the health care services who is fully involved, and the main researcher does not know how to selected patients divided in each group. Data analysis and data collection are also conducted by the project researcher, who has not informed about the project and randomization.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Neurology Department, Bu ali Sina Hospital, South Naderi St., Qazvin, Iran

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Province
Qazvin

Postal code
34197-59811

Approval date
2023-07-16, 1402/04/25

Ethics committee reference number
IR.QUMS.REC.1402.112

Health conditions studied

1

Description of health condition studied
Migraine Headche

ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Comparison of effects on headache indices (duration, severity of clinical symptoms, and frequency of attacks) in riboflavin and amitriptyline groups and comparison of riboflavin and amitriptyline headache indices in the period of one, three months from the start of treatment and investigation of side effects caused by Taking study drugs
Timepoint
In this study, the headache indices in two groups of riboflavin and amitriptyline are investigated in the period of one and three month after starting the treatment.
Method of measurement
In both groups, based on a checklist of patients' demographic information, as well as information related to occupation, duration of headache, type of previously used medication, headache intensity (PAIN SCALE), frequency of attacks per month, number of days of attack and co-morbidity of DM, HTN, VASCULAR DISORDER, PSYCHIATRIC DISORDER, GI DISORDER) are fulfilled by patients in both groups. Patients in the first group (A) has administrated riboflavin at a dose of 100 mg twice a day, and the other group (B) has administrated amitriptyline at a single dose of 25 mg. Then both groups are re-evaluated again after one and three months later in terms of headache indicators. Also, the drug side effects considered in the study including (diarrhea, nausea, vomiting and polyuria) are investigated.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: this study, riboflavin (from Flaviran brand) has administrated to patients at a dose of 200 mg divided into two doses of 100 mg (every 12 hours) up to 3 months (sample number: 36 patients). The side effects and advantages of riboflavin has investigated and the patients enrolled to this study voluntarily after filling out the consent form and initial questionnaire.
Category
Treatment - Drugs

2

Description
Control group: In this study, amitriptyline has administrated to patients at a single dose of 25 mg up to 3 months (sample number: 36 patients). The side effects and advantages of amitriptyline has investigated and the patients enrolled to this study voluntarily after filling out the consent form and initial questionnaire.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin Neurology clinic
Full name of responsible person
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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

Qazvin University of Medical Sciences

Proportion provided by this source
30

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
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Assistant

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable