

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of combined combination of Mg, B12 and intense aerobic exercise on CGRP in women with migraine

Protocol summary

Study aim

Determining the effect of combination of Mg, B12, and intense aerobic exercise on CGRP in women with migraine

Design

A controlled clinical trial with a parallel-group design of 60 Subjects, Randomized by simple randomization method, Phase 2; on 60 patients

Settings and conduct

In this quasi-experimental study, by referring to the office of Dr. Chitsaz, a neurologist, 60 subjects are selected and divided into four groups. Blood samples are taken from patients 48 hours before the start and after the implementation of the training protocol. Intervention group 1: Aerobic exercises, including training with Astrand bike with 60% of maximum heart rate in the first week and 85% of maximum heart rate in the eighth week. Intervention group 2: Supplementation group: One 250 mg magnesium and 1 mg tablets daily Intervention group 3: Aerobic exercises and supplementation. Control group: No intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of migraine by a doctor.
Exclusion criteria: Do not take food supplements in the last 3 months; Lack of sports history in the last 6 months

Intervention groups

Intervention group 1: Aerobic exercises, including training with Astrand bike with 60% of maximum heart rate in the first week and 85% of maximum heart rate in the eighth week. Intervention group 2: Supplementation group: One 250 mg magnesium and 1 mg tablets daily Intervention group 3: Aerobic exercises and supplementation. Control group: No intervention

Main outcome variables

Calcitonin Gene-Related Peptide

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170510033909N12**

Registration date: **2021-07-14, 1400/04/23**

Registration timing: **prospective**

Last update: **2021-07-14, 1400/04/23**

Update count: **0**

Registration date

2021-07-14, 1400/04/23

Registrant information

Name

فرزانه تقیان

Name of organization / entity

دانشگاه آزاد اسلامی. واحد اصفهان

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined combination of Mg, B12 and intense aerobic exercise on CGRP in women with

migraine

Public title
Exercise and migraine

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of migraine by a doctor
Exclusion criteria:
Do not take food supplements in the last 3 months Lack of sports history in the last 6 months

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization;
Randomization Tool: Random Number Table;
Randomization Unit: Individual; In order to use a table of random numbers, the researcher will first determine the reading position of the table numbers. The numbers will then be considered for different groups. For example, zero to twenty-four for intervention A, twenty-five to forty-nine for intervention B, fifty to seventy-four for group C, and seventy-five to nine for group D. Then we will touch one of the numbers and move in one of the predetermined directions. The numbers will be recorded and assigned to four groups: aerobic exercise, Mg intake, B12, combination and control. In order to hide random allocation, the method of coded boxes with random sequence will be used. This method uses a number of boxes that are numbered randomly. Adequate sealing of the boxes, their apparent similarity and their weight will be ensured.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee on Research Islamic Azad University - Isfahan Branch (Khorasgan)
Street address
University Blvd, Arghavanie, East Gay Street, Isfahan
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Province
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Postal code
8155139998
Approval date
2021-06-02, 1400/03/12
Ethics committee reference number
IR.IAU.KHUISF.REC.1400.056

Health conditions studied

1

Description of health condition studied

migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Calcitonin Gene-Related Peptide

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Serum concentration of CGRP by ELISA method using the Eastbiopharm Monobind CHINA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : Intense aerobic exercise:The training program consists of three parts: warm-up, main stage and cooling. The warm-up and cooling phase includes 10 minutes and the main phase of training with the Astrand bike with 60% of the maximum heart rate in the first week and 85% of the maximum heart rate in the eighth week.

Category

Rehabilitation

2

Description

Intervention group 2 : One tablet of 250 mg of magnesium and 1 mg of B12 daily for 8 weeks

Category

Lifestyle

3**Description**

Intervention group 3 : Supplementation and aerobic exercise: Exercise program includes exercise with Astrand bike with 60% of maximum heart rate in the first week and 85% of maximum heart rate in the eighth week. Take one 250 mg magnesium and 1 mg B12 tablet daily for 8 weeks.

Category

Lifestyle

4**Description**

Control group: No intervention, only follow up

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neurologist

Full name of responsible person

Ahmad Chitsaz

Street address

Arad building, next to Sina hospital, Shamsabadi street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University, Isfahan Branch (Khorasgan),
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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

Islamic Azad University, Isfahan Branch (Khorasgan),
Research Deputy

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**

Islamic Azad University

Full name of responsible person

Farzaneh taghian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address

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

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