

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Survival on 8 weeks of endurance training effectiveness with different intensities on plasma level of the content of Calcitonin Gene-Related Peptide (CGRP) and Nitric Oxide (NO) in Patients with Migraine Disorder

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

1. Objectives: the purpose of this study is determination 8 Weeks Endurance Training Effectiveness with Different Intensities on Plasma Level of the Content of Calcitonin Gene-Related Peptide (CGRP) and Nitric Oxide (NO) in Patients with Migraine Disorder; 2. the number of 54 people with migraine disorder who have inclusion criteria and will confirmed by neurologist randomly will be assigned into 3 groups including control, Moderate Intensity Aerobic training, and High Intensity Aerobic training; 3. the research totally will take place 4 months that the observation will happen in the first and last months and training protocols will perform in the second and third months. For variables measuring including CGRP and NO, blood samples will be obtained 48 hours pre and post of training protocols; 4- inclusion criteria including: A. The age of patients should be on range of 18 to 45 years; B. the patients have not been involving in regular exercise activity experience since 6 months ago; and C. they do not have experience in chronic diseases, and exclusion criteria including: The patient do extra exercise training; and the patient would be absent in 3 sessions continuously during exercise training; 5. two Moderate and High intensities aerobic training that will perform 40 and 30 minute, respectively, are interventions; 6- the main outcomes are CGRP and NO (as primary outcomes) and migraine headache indexes (intensity, duration, and frequency) (as secondary outcomes).

Last update:

Update count: **0**

Registration date

2015-12-05, 1394/09/14

Registrant information

Name

Abdolhossein Parnow

Name of organization / entity

Razi University of Kermanshah

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survival on 8 weeks of endurance training effectiveness with different intensities on plasma level of the content

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015100910824N2**

Registration date: **2015-12-05, 1394/09/14**

of Calcitonin Gene-Related Peptide (CGRP) and Nitric Oxide (NO) in Patients with Migraine Disorder

Public title

Physical Activity and Migraine

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: The age of patients should be on range of 18 to 45 years; the patients have not been involving in regular exercise activity experience since 6 months ago; they do not have experience in chronic disease such as cardiovascular disease, hypertension, diabetes, arthritis, cancer, asthma, HIV, meningitis and Multiple Sclerosis; The migraine headache (aura and without aura) must be confirmed by neurologist; and inclusion criteria in the VO2max testing is 20 ml/min/kg. Exclusion criteria: The patient do extra exercise training; the patient be absent more than 3 session continuously during exercise training; and the patient voluntary give up the training program during or any of the stages of research.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

randomized with using numerical table

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research, University of Medical Sciences, Shahid Beheshti Bulvar, Kermanshah

City

Kermanshah

Postal code**Approval date**

2015-04-28, 1394/02/08

Ethics committee reference number

kums.rec.1394.15

Health conditions studied**1****Description of health condition studied**

Maigraine

ICD-10 code

2010

ICD-10 code description

Use additional external cause code (Chapter XX), if desired, to identify drug, if drug-induced.

Primary outcomes**1****Description**

CGRP, NO

Timepoint

Blood sampling 48 hours before and after innervation

Method of measurement

Using CGRP and NO ELISA Kits

Secondary outcomes**1****Description**

Migraine Index (intensity-frequency-duration)

Timepoint

One month before and one month after of the intervention

Method of measurement

Migraine Index questionnaire

Intervention groups**1****Description**

Intervention 1: Moderate Intensity Aerobic training will be performed with 13-15 Borg RPE Scale for 40 minute per session.

Category

Other

2**Description**

Intervention 2: High Intensity Aerobic training will be performed with 15-17 Borg RPE Scale for 30 minute per session.

Category

Other

3

Description

Control Group: There is no any intervention in this group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Zahra Pairo

Street address

Zanbagh-e-sharghi, Baharestan, Bahar, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Kermanshah
University of Medical Sciences

Full name of responsible person

Behroz Hamzeh

Street address

Vice Chancellor for Research and Technology,
Building Number 2, Shahid Beheshti Boulevard

City

Kermanshah

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research of Kermanshah 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

Razi University

Full name of responsible person

Zahra Pairo

Position

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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