Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Survy 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

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 moths 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 rage 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).

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015100910824N2**
Registration date: **2015-12-05, 1394/09/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-05, 1394/09/14

Registrant information

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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

Survy 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

Public title
Physical Activity and Migraine
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: The age of patients should be on rage 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 Bulvard, 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 mount 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
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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 Behehshti 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

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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