Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of 8 Weeks of Aerobic endurance Exercise Training with Moderate Intensity on Permeability Inflammatory Indicators of Matrix Metalloproteinases and Specific Tissue Inhibitors of MMPs in Migraine Patients

Protocol summary

Study aim

We hypothesized that moderate aerobic training lowers the serum level of S100B and MDA or increases the serum level of SOD and improves headache indices and general health status in wMIG.

Design

The study is a randomized controlled clinical trial (RCT) with a semi-experimental design (three groups with pre- and post-testing).

Settings and conduct

Imam reza Hospital, Kermanshah

Participants/Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) no history of regular exercise in the previous 6 months; (2) no chronic diseases such as cardiovascular, hypertension, diabetes, arthritis, cancer, asthma, AIDS, meningitis or MS; (3) confirming headache by the neurologist; (4) Having an age range of 18 to 45 years. Exclusion criteria comprised: (1) situations that researchers understood during the research period, such as pregnancy, breastfeeding and abuse of drugs or alcohol; (2) participation in any additional exercise training programmes; (3) no interest on the part of the volunteer in continuing or making a change in their personal life schedule; (4) contracting COVID-19, and 5) voluntary finished the protocol.

Intervention groups

1) exercise+migraineurs group (doing 8 weeks of endurance exercise training, running and taking medicine prescribed by the doctor). 2) non-exercise+migraineurs group (only taking medicine prescribed by the doctor). 3. A healthy control group (without medicine and healthy).

Main outcome variables

matrix metalloproteinases-2 (MMP-2), matrix metalloproteinases-9 (MMP-9), Inhibitors of matrix metalloproteinases-1(TIMP-1),Inhibitors of matrix metalloproteinases-2 (TIMP-2), S100 calcium-binding protein B(S100B)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120912010824N4**
Registration date: **2023-09-30, 1402/07/08**
Registration timing: **retrospective**

Last update: **2023-09-30, 1402/07/08**
Update count: **0**

Registration date

2023-09-30, 1402/07/08

Registrant information

Name

Abdolhossein Parnow

Name of organization / entity

Razi University of Kermanshah

Country

Iran (Islamic Republic of)

Phone

+98 83 1428 3275

Email address

a.parnow@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-30, 1400/02/10

Expected recruitment end date

2021-07-11, 1400/04/20

Actual recruitment start date

2021-05-10, 1400/02/20

Actual recruitment end date

2021-11-06, 1400/08/15

Trial completion date

2023-09-21, 1402/06/30

Scientific title

The Effect of 8 Weeks of Aerobic endurance Exercise Training with Moderate Intensity on Permeability Inflammatory Indicators of Matrix Metalloproteinases and Specific Tissue Inhibitors of MMPs in Migraine Patients

Public title

Moderate aerobic exercise and Migraine disease

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

no chronic diseases such as cardiovascular, hypertension, diabetes, arthritis, cancer, asthma, AIDS, meningitis or MS no history of regular exercise in the previous 6 months confirming headache by the neurologist

Exclusion criteria:

contracting COVID-19

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

First, for the two groups of training and control patients, according to the entry and exit criteria, 30 people were introduced by the attending physician of the Kermanshah migraine patient community. A simple random model was used to divide into two groups, and a random number table tool was used for this model. The random sequence was prepared using Random software. For the healthy group, 15 people were selected as available sampling.

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

Research Working Group at the Sports Sciences Research Institute

Street address

Motahari Street

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2022-06-24, 1401/04/03

Ethics committee reference number

IR.SSRC.REC.1402.100

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

matrix metalloproteinases (MMPs) and specific tissue inhibitors of MMPs

Timepoint

48 hours before and after the training protocol

Method of measurement

blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the group of migraine patients who underwent 12 weeks of indoor aerobic exercise training, which lasted three sessions a week for one hour in each session.

Category

Rehabilitation

2

Description

Control group: group of migraine patients without

exercise training.

Category
Rehabilitation

3

Description
Control group: group of healthy people without any disease and without exercise.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
بیمارستان امام رضا کرمانشاه

Full name of responsible person
زهرا پیرو

Street address
سرخه لیژه

City
کرمانشاه

Province
Kermanshah

Postal code
6714414874

Phone
+98 83 3428 3276

Email
parnowabdolhossein@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Payam Sari Aslani

Street address
sorkhe lisheh

City
Kermanshah

Province
Kermanshah

Postal code
6714414874

Phone
+98 912 831 5374

Email
psariaslani@kums.ac.ir

Grant name
no funded

Grant code / Reference number
00

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
personal

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Zahra Pairo

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Sport Medicine

Street address
Razi University

City
Kermanshah

Province
Kermanshah

Postal code
6714414874

Phone
0834283276

Email
zahrapairo@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Abdolhossein Parnow

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
exercise physiology

Street address
Razi university

City
Kermanshah

Province
Kermanshah

Postal code
6714414874

Phone
+98 83 3428 3276
Email
parnowabdolhossein@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Abdolhossein Parnow
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
exercise physiolgy
Street address
Razi University
City
Kermanshah
Province
Kermanshah
Postal code
6714414874
Phone
+98 83 3428 3276
Email
parnowabdolhossein@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
No known time
When the data will become available and for how long
No known time
To whom data/document is available
researchers
Under which criteria data/document could be used
Research using
From where data/document is obtainable
Corrsponding author
What processes are involved for a request to access data/document
Email
Comments
No