

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Payam Sari Aslani

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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

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Abdolhossein Parnow

Position

Associate professor

Latest degree

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Other areas of specialty/work

exercise physiology

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Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

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Position

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Latest degree

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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

Corresponding author

What processes are involved for a request to access data/document

Email

Comments

No