

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of exercise in different environmental conditions on the heart rate variability of healthy young men

Protocol summary

Study aim

Effect of exercise training in different conditions (aerobic exercise in dry and water conditions) on heart rate variability

Design

A clinical trial with a control group based on the training environment with parallel training groups and a randomized, double-blinded design

Settings and conduct

The location of the study was conducted at the Sport Physiology Laboratory of Mohaghegh Ardebil University. In order to eliminate the bias caused by the subject's knowledge and evaluator, Heart Monitor Holter system results and the result of the study are conducted in a blind, two-way study. Given that the recorded frequencies of heart rate variability are transferred to the memory card of the Holter monitor card, it is normal that the subject and the assessing person do not know the type of effect of the intervention on the change in heart rate, and the subject is quite naturally just his practice according to the plan, and by recording the information device from his body, and at the stage of analysis, the researcher himself will have access to the recorded information.

Participants/Inclusion and exclusion criteria

The entry requirement is having age between 20 and 30 years old and having maximum oxygen intake between 48 and 55 ml per kg of body weight. The condition for leaving the study is injuries during training or symptoms of heart disease.

Intervention groups

Performing an aerobic exercise on a treadmill and aerobic exercise in a water environment with a temperature of 26 ° C and water at a temperature of 38 ° C and control group without exercise. Equivalent energy was applied to intervention groups.

Main outcome variables

Heart rate variability indexes include low frequency waves, high frequency waves, very low frequency waves,

total power, percentage of sympathy system overcrowding and percentage of parasympathetic system overcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180724040579N1**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **retrospective**

Last update: **2019-04-08, 1398/01/19**

Update count: **1**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Asgar Iranpour

Name of organization / entity

University of Mohaghegh Ardebili

Country

Iran (Islamic Republic of)

Phone

+98 45 3371 7240

Email address

iranpoursport@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-05, 1397/05/14

Expected recruitment end date

2018-09-04, 1397/06/13

Actual recruitment start date

2018-08-04, 1397/05/13

Actual recruitment end date

2018-09-04, 1397/06/13

Trial completion date

2018-09-04, 1397/06/13

Scientific title

The effect of exercise in different environmental conditions on the heart rate variability of healthy young men

Public title

heart rate variability of healthy young men

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Having the maximum oxygen consumption in the range of 50-48 ml per kg of body weight per min having no exercise plan outside the plan not having any skin allergy to exercise in the aquatic environment having a 20 to 30 year age

Exclusion criteria:

Seeing any cardiac failure in the diagnosis of a physician present in the research team during the test Exit of the research due to irregular participation in training any injuries during training

Age

From **20 years** old to **30 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **165**

Actual sample size reached: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, simple randomization method with random number Table method was used . This table contains a bunch of numbers that are randomly drawn in the form of a table without a specific pattern and order. The numbers directions(Left, right, up, down) were first determined by the researcher to read the numbers and then the numbers were considered for different research groups. In the next step, the researcher randomly placed on one of the numbers and moved in the preset direction and recorded the numbers for that direction in the target group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to eliminate the bias caused by the subject's knowledge and evaluator, Heart Monitor Holter system results and the result of the study are conducted in a blind, two-way study. Given that the recorded frequencies of heart rate variability are transferred to the memory card of the Holter monitor card, it is normal that

the subject and the assessing person do not know the type of effect of the intervention on the change in heart rate, and the subject is quite naturally just his practice according to the plan, and by recording the information device from his body, and at the stage of analysis, the researcher himself will have access to the recorded information.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ardabil Medical Ethics Committee

Street address

Deputy Research and Technology, Ardabil Complex University, Daneshgah st, Ardabil

City

Ardebil

Province

Ardabil

Postal code

56189-85991

Approval date

2018-02-04, 1396/11/15

Ethics committee reference number

IR.ARUMS.REC.1396.217

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

Cardiovascular disease

ICD-10 code

I46.1

ICD-10 code description

Sudden cardiac death, so described

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

cardiovascular response

Timepoint

After 20 consecutive workouts

Method of measurement

Use the My Patch & Vx3 + Monitor Holler

Secondary outcomes

Iranpoursport@yahoo.com

1

Description

Sudden cardiac death prevention

Timepoint

20 dayes

Method of measurement

By Analyzing Heart Rate Variability Data

Intervention groups

1

Description

intervention group: exercise in Drought condition(treadmill)

Category

N/A

2

Description

Intervention group: exercise in warm water condition

Category

N/A

3

Description

Intervention group: exercise in normal water condition

Category

N/A

4

Description

Control group: no extra work

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Mohageg Ardebili

Full name of responsible person

Asghar Iranpour

Street address

University Street

City

Ardebil

Province

Ardabil

Postal code

5653178171

Phone

+98 45 3351 8533

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Univercity of Mohageg Ardebili

Full name of responsible person

Lotfali Bolboli

Street address

University Street

City

Ardebil

Province

Ardabil

Postal code

5653178171

Phone

+98 45 3351 8533

Email

Lotfalibolboli@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Univercity of Mohageg Ardebili

Proportion provided by this source

50

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

University of Mohageg Ardebili

Full name of responsible person

Asghar Iranpour

Position

PHD Student

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Asghar Iranpour

Position

PHD student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Share the results of a person's health

When the data will become available and for how long

1 month

To whom data/document is available

subjects

Under which criteria data/document could be used

In order to be aware of a healthy exercise environment

From where data/document is obtainable

University of Mohaghegh Ardabili, Department of Physical Education and Sport Sciences

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

Apply to the Physical Education Department and receive data

Comments