Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The Effect of Iron Supplementation on the Factors Affecting the Aerobic Capacity of Women Athletes

Protocol summary

Study aim
The Effect of Iron Supplementation on the Factors Affecting the Aerobic Capacity of Women Athletes

Design
Clinical trial with control group and supplement group, double-blind, randomized, phase 3 on 14 patients, Excel software was used to evaluate the data.

Settings and conduct
Aerobic capacities of the participants will be measured using the Bruce test and the use of a gas analyzer (Gas Analyzer: Cortex Biophysic Germany), which will be manually entered into the treadmill data. In this way, after installing the device's heart rate sensor on the subject's chest and identifying it by the device, the subject's information including age and weight is entered and finally the Bruce test begins and the person performs the test with increasing intensity until the time of exhaustion. The end of maximum oxygen consumption of people is calculated and recorded by the device. The intervention with iron or placebo begins after measuring the research variables and continues for 3 weeks, and after the end of the three-week period, the subjects are re-tested. Both researchers and participants were blinded.

Participants/Inclusion and exclusion criteria
Completing the informed consent form and having full consent, not having any types of special and chronic diseases, the type and time of drug use (if used), not having pain in a specific area of the body

Intervention groups
Supplemental group: daily recipient of 100 mg of iron (a 100 mg tablet of polymaltose iron trihydroxide complex) for 3 weeks Control group: receiving 100 mg of placebo daily (two mouth deodorizing tablets that are the same color and shape as iron tablets and are completely ineffective) for 3 weeks

Main outcome variables
Maximum aerobic power, pressure perception scale, time to reach stasis, pulmonary ventilation and respiratory efficiency including EQO2 and EQCO2

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230816059165N1**
Registration date: **2023-11-04, 1402/08/13**
Registration timing: **retrospective**

Last update: **2023-11-04, 1402/08/13**
Update count: **0**

Registration date
2023-11-04, 1402/08/13

Registrant information

Name
Ghazal Safa

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 4220 7370

Email address
ghazal.safa94@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-08, 1401/03/18

Expected recruitment end date
2022-06-15, 1401/03/25

Actual recruitment start date
2022-06-22, 1401/04/01

Actual recruitment end date
2022-06-30, 1401/04/09

Trial completion date

2022-08-24, 1401/06/02

Scientific title
The Effect of Iron Supplementation on the Factors Affecting the Aerobic Capacity of Women Athletes

Public title
The Effect of Iron Supplementation on the Factors Affecting the Aerobic Capacity of Women Athletes

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
Completing the informed consent form and having full consent to participate in the current research Not having a variety of special and chronic diseases Not having pain in a particular area of the body Type and time of drug administration (if used)

Exclusion criteria:

Age
From **16 years** old to **33 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **20**
Actual sample size reached: **14**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method with individual randomization unit: In this way, the 14 subjects of the present study were divided into two groups of 7 by the laboratory manager without considering any specific case among them.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the present study, the subjects had no information about which of the two iron supplement and placebo groups they had taken, and they were kept blind in the study. The administration of the supplement and placebo was done by the laboratory official taking into account ethical considerations, so that they knew which package contained iron and which one contained placebo, and gave iron supplement to one group and placebo to another group. Is. After this step was done, only the researcher and supervisor were informed. The doctor in charge of the present study has also approved the permission to use iron supplements and has been involved in all stages of the work.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University Research Ethics Committee

Street address
No. 54, Saadi St., Khajoo Crossroad; Sirjan

City
Sirjan

Province
Kerman

Postal code
7814615431

Approval date
2022-11-09, 1401/08/18

Ethics committee reference number
IR.US.REC.1401.023

Health conditions studied

1

Description of health condition studied
The Effect of Iron Supplementation on the Factors Affecting the Aerobic Capacity of Women Athletes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Investigating the percentage of changes and significant differences between the two studied groups in the aerobic capacity of female handball players

Timepoint
Measuring blood volume of the participants before the intervention and 21 days after consuming 100 mg of iron (a 100 mg tablet of polymaltose iron trihydroxide complex)

Method of measurement
Maximum aerobic capacity, pressure perception scale, time to reach paralysis, lung ventilation and respiratory efficiency including EQO2 and EQCO2 using Bruce test and using gas analyzer (Gas Analyzer: Cortex Biophysik Germany) which will be entered manually in the treadmill data. is measured and at the end the aerobic capacities of people are calculated and recorded by the device.

Secondary outcomes

1

Description
No significant difference was observed between the two

studied groups in respiratory indices (Vo2max; RPE; VE; TTE; EQO2; EQCO2).

Timepoint

Measuring blood volume of the participants before the intervention and 21 days after consuming 100 mg of iron (a 100 mg tablet of polymaltose iron trihydroxide complex)

Method of measurement

Maximum aerobic capacity, pressure perception scale, time to reach paralysis, lung ventilation and respiratory efficiency including EQO2 and EQCO2 using Bruce test and using gas analyzer (Gas Analyzer: Cortex Biophysik Germany) which will be entered manually in the treadmill data. is measured and at the end the aerobic capacities of people are calculated and recorded by the device.

Intervention groups

1

Description

Intervention group: daily intake of 100 mg of elemental iron (one 100 mg tablet of polymaltose iron trihydroxide complex for 3 weeks), every night 1 hour before sleep. Manufacturer: Viralian Group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz women's handball team

Full name of responsible person
Ghazal Safa

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No. 54, Saadi St., Khajoo Crossroad., Sirjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Shiraz

Full name of responsible person
Ghazal Safa

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Shiraz

Proportion provided by this source

100

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
The University of Shiraz

Full name of responsible person
Ghazal Safa

Position
Fitness Trainer

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Shiraz

Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because of students' unauthorized use of data and data creation through other people's data, which ultimately devalues other people's research.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Only part of the data, such as the main outcome information, will be available only to researchers working in academic and scientific institutions after de-identifying individuals.

When the data will become available and for how long
The access period starts from June 2023

To whom data/document is available
It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Researchers working in academic and scientific institutions can use only part of the data, such as the information related to the main outcome, in their scientific researches and refer to the results obtained from them, but the right of any new analysis on the delivered data, do not have.

From where data/document is obtainable
Full name of the researcher: Ghazal Safa/Gmail: ghazal.safa94@gmail.com

What processes are involved for a request to access data/document
Only a part of the data, such as the information related to the main outcome, will be sent to researchers working in academic and scientific institutions after receiving the e-mail from the researcher.

Comments