Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of eight weeks of aerobic exercise and garlic supplementation on fatigue and cardiovascular risk factors in women with rheumatoid arthritis

Protocol summary

Study aim

Investigation of effect of 8 weeks of aerobic exercise and garlic supplementation on fatigue and cardiovascular risk factors in women with rheumatoid arthritis.

Design

Pre-test and post-test design with parallel, double-blind, randomized groups using variable block method will be performed on 40 patients.

Settings and conduct

The present study will be conducted at Sistan and Baluchestan University. For this purpose, three groups are subjected to three interventions: garlic consumption, aerobic exercise and garlic consumption + aerobic exercise. For blindness, the third group receives placebo in addition to exercise. Only supervisor knows the content of the capsules used by the exercise groups.

Participants/Inclusion and exclusion criteria

Participants in this study are women with rheumatoid arthritis. Inclusion criteria: Rheumatoid arthritis disease, age 27 to 45 years and being of childbearing age. Exclusion Criteria: Cardiovascular disease.

Intervention groups

Intervention group 1: Will do aerobic exercise for 8 weeks with a ergometer, 3 sessions/week and each session for 60 minutes (20 minutes of warm-up and cooling, 30 to 40 minutes of exercise with an intensity of 70% of VO2max) During this time, receives a placebo(Guaranteed cornstarch made by Etminan Hadaf Toos Company in the amount of 500 mg in coatings similar to garlic supplement capsules by the researcher))twice a day. Intervention group 2: In addition to the aerobic exercise program, will take a garlic supplement(under the brand name Garcin, manufactured by Gol Daroo Company) twice/day at a dose of 500 mg during the research period. Intervention group 3: For 8 weeks, receive only garlic supplement, 500 mg, twice/day.

Main outcome variables

Fatigue; Systolic blood pressure; Low Density Lipoprotein; total Cholesterol.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041097N5**
Registration date: **2022-02-01, 1400/11/12**
Registration timing: **retrospective**

Last update: **2022-02-01, 1400/11/12**
Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

Reza Delavar

Name of organization / entity

The University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

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+98 54 3113 2674

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-09-16, 1400/06/25

Actual recruitment start date

2021-11-06, 1400/08/15

Actual recruitment end date

2021-11-11, 1400/08/20

Trial completion date

2022-06-03, 1401/03/13

Scientific title

The effect of eight weeks of aerobic exercise and garlic supplementation on fatigue and cardiovascular risk factors in women with rheumatoid arthritis

Public title

Effect of aerobic exercise and garlic consumption on rheumatoid arthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women with rheumatoid arthritis Women with rheumatoid arthritis who are of childbearing age. Women with rheumatoid arthritis aged 27 to 45 years.

Exclusion criteria:

Women with rheumatoid arthritis who also have cardiovascular disease.

Age

From **27 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation is done by simple randomization method. First, 3 groups based on the number of participants in each group and the number of groups required for the trial (placebo, exercise, exercise and placebo), are formed and then a 2 digit code is given to each subject without any criteria from 01 to 48. Then a number is selected in the table of random numbers, with the eyes closed, and in the row to the right of the desired number, up to 16 two-digit numbers less than 48 for the first group, 16 second two-digit numbers for the second group and 16 third two-digit numbers for the third group will be considered.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present trial, there are two groups of exercise, one receiving supplement and the other receiving placebo. The Supervisor is the only one who is aware of the contents of the capsules containing the supplement and placebo, and provides these capsules to the evaluator students for the use of the subjects in the supplement and exercise + supplement groups. Thus, participants, evaluators and statistical analysts do not know which group is a exercise group and which group is a exercise + supplement group.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sistan and Baluchestan University.

Street address

Central Organization of Sistan and Baluchestan University, University Blvd, Zahedan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

۹۸۱۶۷-۴۵۸۴۵

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.USB.REC.1399.001

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M05.04

ICD-10 code description

Felty's syndrome, hand

Primary outcomes

1

Description

Systolic blood pressure above 14 mm Hg.

Timepoint

24 hours before and 24 hours after the first and last session of the exercise program.

Method of measurement

By arm blood pressure monitor

2

Description
Total cholesterol above 250 mg per deciliter.
Timepoint
24 hours before and 24 hours after the first and last session of the exercise program.
Method of measurement
Total cholesterol diagnostic kit made by Pars Azmoun company by photometric method

3

Description
Blood LDL level above 160 mg per deciliter.
Timepoint
24 hours before and 24 hours after the first and last session of the exercise program.
Method of measurement
Low density lipoprotein diagnostic kit made by Pars Azmon Company by photometric method

4

Description
Fatigue rate above 3 points
Timepoint
24 hours before and 24 hours after the first and last session of the exercise program.
Method of measurement
Fatigue Symptom Inventory questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: This group pedals on the ergometer (Body sculpture brand made in China)for eight weeks, 3 sessions per week, in each session after 10 minutes of warm-up, with an intensity of 70% of the maximum oxygen consumption, and then cools down for 10 minutes and daily receives 2 rounds of placebo (corn starch under the Zamen brand, manufactured by Etminan Hadaf Toos Company, which was prepared in the amount of 500 mg in coatings similar to garlic supplement capsules by the researcher).
Category
Behavior

2

Description
Second intervention group: This group pedals on the ergometer for eight weeks, 3 sessions per week and in each session after 10 minutes of warm-up, with an intensity of 70% of the maximum oxygen consumption, and then cools down for 10 minutes. Take 2 times a day garlic supplement with Garcin brand made by Goldaro company, Iran in a dose of 500 mg.
Category
Treatment - Other

3

Description
Third intervention group: This group receives 500 mg of garlic supplement(with brand of Garcin produced by Gol daro Company), twice a day for eight weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ibn abitaleb Hospital
Full name of responsible person
Mahnaz Sandoughi
Street address
Ali Ibn Abitaleb Hospital, Salamat Blvd, Persian Gulf Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Sistan and Baluchestan
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dor_kordi@science.usb.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Sistan and Baluchestan

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 Sistan and Baluchestan

Full name of responsible person

Reza Delavar

Position

Assiatant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Person responsible for updating data

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Other areas of specialty/work

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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

Subjects' information is shared with other researchers after being Unrecognizable.

When the data will become available and for how long

After the publication of the final research report.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Citing the findings by citing the source

From where data/document is obtainable

By email address

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

After receiving the request via email and reviewing the request by the scientific officer of the research, will be answered.

Comments