

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 Etmiran 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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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

98167-40840

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 Goldaro 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

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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

Full name of responsible person

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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 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
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Position
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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