

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Acute and chronic effects of a course of aerobic exercise training and garlic supplementation on serum levels of interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with Rheumatoid Arthritis

#### Protocol summary

##### Study aim

Evaluation of acute and chronic effects of aerobic exercise and garlic supplementation on serum levels of interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with rheumatoid arthritis

##### Design

A clinical trial with parallel, double-blind, randomized groups on 45 patients. The variable block method is used for randomization.

##### Settings and conduct

The training program will include 8 weeks of work with a ergometer bicycle, 3 sessions/week and each session for 60 minutes with a heart rate of 70% of the maximum heart rate. Exercise+supplement group, in addition to exercise, receive garlic supplement (at a dose of 500 mg twice/day). Exercise group+placebo, in addition to exercise, receive starch with a garlic-like appearance, and the supplement group, only receives garlic supplements. Exercises will performed in the Moin Stadium of Sistan and Baluchestan University and diagnostic tests are performed in the laboratory of Dr. Dabiri in Zahedan. For blindness, subjects and evaluators will be unaware of the exercise+placebo and supplement+exercise groups.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Catching Rheumatoid arthritis

Exclusion Criteria: Cardiovascular disease, pregnancy and menopause

##### Intervention groups

1- Exercise group: 8 weeks of work with a ergometer bicycle, 3 sessions per week and each session for a duration 60 minutes with a heart rate of 70% of the maximum heart rate. 2- Exercise+supplement group: In addition to the 8-week exercise program, they also take garlic supplements for 8 weeks (at a dose of 500 mg twice a day). 3- Supplement group: receives only garlic supplement for 8 weeks.

##### Main outcome variables

Serum levels of IL-6; Erythrocyte sedimentation rate and changes in fatigue due to aerobic exercise and garlic supplementation in rheumatoid arthritis.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180923041097N4**

Registration date: **2021-11-27, 1400/09/06**

Registration timing: **retrospective**

Last update: **2021-11-27, 1400/09/06**

Update count: **0**

##### Registration date

2021-11-27, 1400/09/06

##### Registrant information

##### Name

Reza Delavar

##### Name of organization / entity

The University of Sistan and Baluchestan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3113 2674

##### Email address

delavar@ped.usb.ac.ir

##### 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**

2022-03-11, 1400/12/20

**Scientific title**

Acute and chronic effects of a course of aerobic exercise training and garlic supplementation on serum levels of interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with Rheumatoid Arthritis

**Public title**

The effect of aerobic exercise and garlic supplementation on interleukin 6 (IL6), erythrocyte sedimentation rate (ESR) and fatigue in women with rheumatoid arthritis

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Rheumatoid arthritis patients Women who are menstruating The age range of 25 - 45 years

**Exclusion criteria:**

Cardiovascular disease Menopausal women

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

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

**Sample size**

Target sample size: **45**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation method used with variable blocks. 3 groups of 15 people were considered and the subjects were randomly divided into three groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

- Participants in the experimental groups (supplement and placebo) are unaware of taking the supplement or placebo. - In addition to participants, outcome assessors are unaware of complementary and placebo groups

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee, Sistan and Baluchestan University

**Street address**

Central Organization of Sistan and Baluchestan University, University Blvd.

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816745845

**Approval date**

2021-04-22, 1400/02/02

**Ethics committee reference number**

IR.USB.REC.1400.020

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

Rheumatoid Arthritis

**ICD-10 code**

M05.049

**ICD-10 code description**

Felty's syndrome, unspecified hand

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

Inflammatory factor interleukin-6, the amount of which is above 20 pg/ml by ELISA kit.

**Timepoint**

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

**Method of measurement**

Interleukin-6 ELISA kit

**2****Description**

Erythrocyte Sedimentation Rate above 35 mm/hr.

**Timepoint**

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

**Method of measurement**

Westergren method.

### 3

#### **Description**

Fatigue rate, which was considered above 3 on average

#### **Timepoint**

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

#### **Method of measurement**

Fatigue Severity Inventory (FSI) Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group 1: A group that performs 8 weeks of aerobic exercise, 3 sessions per week and 1 hour per session with an intensity of 70% of the maximum heart rate on the ergometer bicycle.

#### **Category**

Behavior

#### 2

#### **Description**

Intervention group 2: The group that in addition to aerobic exercise training also receives a garlic supplement at a dose of 500 mg, twice a day.

#### **Category**

Treatment - Other

#### 3

#### **Description**

Intervention group 3: The group that receives only garlic supplement at a dose of 500 mg twice a day for 8 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**

Persian Gulf Highway - Salamat Boulevard - Ali Ibn Abitaleb Hospital

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816743463

##### **Phone**

+98 54 3337 2151

#### **Fax**

#### **Email**

public@zaums.ac.ir

#### **Web page address**

https://zaums.ac.ir/sites.page

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Zahedan University of Medical Sciences

##### **Full name of responsible person**

Mahnaz Sandoughi

##### **Street address**

ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816743463

##### **Phone**

+98 54 3337 2151

##### **Email**

public@zaums.ac.ir

##### **Web page address**

https://zaums.ac.ir/default.page

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Zahedan University of Medical Sciences

#### **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**

University of Sistan and Baluchestan

##### **Full name of responsible person**

Reza Delavar

##### **Position**

Assistant Professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Exercise Physiology

**Street address**

Department of Sport Sciences, Faculty of Psychology and Educational Sciences, University of Sistan and Baluchestan, , University Blvd.

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816745845

**Phone**

+98 54 3113 6724

**Email**

delavar@ped.usb.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of Sistan and Baluchestan

**Full name of responsible person**

Reza Delavar

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise Physiology

**Street address**

Department of Sport Sciences, Faculty of Psychology and Educational Sciences, University of Sistan and Baluchestan, , University Blvd.

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816745845

**Phone**

+98 54 3113 6724

**Email**

delavar@ped.usb.ac.ir

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

University of Sistan and Bluchestan

**Full name of responsible person**

Reza Delavar

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise Physiology

**Street address**

Department of Sport Sciences, Faculty of Psychology and Educational Sciences, university of Sistan and Baluchestan, University Blvd

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816745845

**Phone**

+98 54 3113 6724

**Email**

delavar@ped.usb.ac.ir

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data related to the subjects after their non-identification and information data related to the main outcome

**When the data will become available and for how long**

From 2023/03/11

**To whom data/document is available**

Researchers working in universities

**Under which criteria data/document could be used**

All interested researchers

**From where data/document is obtainable**

By email address: delavar@ped.usb.ac.ir

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

After reviewing the application received by the scientific responsible for research, the request will be answered via email.

**Comments**