

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A Comparison of Effect of Aerobic Exercise with Saffron Pills on CRP levels and Quality of Life in Fibromyalgia Patients

Protocol summary

Study aim

Determining the Effects of Aerobic Exercise and Saffron Consumption on CRP and Quality of Life in Fibromyalgia Patients

Design

Clinical trial with control group, with factorial groups, randomized, phase 3 on 32 patients.

Settings and conduct

The research method is quasi-experimental with pretest-post test design. Population of this study consisted of women with the age of 25-50 years with fibromyalgia referring to Imam Khomeini Hospital in Sari. The placebo and Saffron are placed inside the capsule in exactly the same way, participants and researchers will not be aware of the type of medication received. Finally, study hypotheses in the study groups were examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being infected to Fibromyalgia ,Lack of Metabolic Diseases , Menopause ,Do not consume energetic substances such as: Vitamins ,Dietary Supplements, Herbs Exclusion criteria:Consumption Cigarettes and Alcoholic beverages ,Having Regular Exercise ,Consumption history Antidepressants

Intervention groups

1- Aerobic training group-Placebo, 2-Drug Intervention Group, 3-Drug-exercise group (Combined), 4- Control group(placebo) Aerobic exercise for six weeks (three sessions per week) consisted of 60-70% of maximal heart rate training for 24 to 39 minutes, under the control of a physician. The intervention time for all 4 groups were 6 weeks. The Drug group and the Drug-exercise group took 30 mg once daily for 6 weeks. The aerobic-placebo and control group took a placebo capsule (30 mg of starch) prepared by Green Plants Company once a day for 6 weeks according to the doctor's instructions.

Main outcome variables

Measuring resting heart rate Measuring the waist to hip ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191125045496N2**

Registration date: **2021-01-16, 1399/10/27**

Registration timing: **retrospective**

Last update: **2021-01-16, 1399/10/27**

Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

Mostafa Behzad Khamislo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3310 9230

Email address

mostafabehzadkh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-10-23, 1398/08/01

Trial completion date

2020-11-21, 1399/09/01

Scientific title

A Comparison of Effect of Aerobic Exercise with Saffron Pills on CRP levels and Quality of Life in Fibromyalgia Patients

Public title

Evaluation of the Effect of Aerobic Exercise and Saffron Consumption in Fibromyalgia Patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Being infected to Fibromyalgia Lack of Metabolic Diseases, Menopause Do not consume energetic substances such as: Vitamins, Dietary Supplements, Herbs

Exclusion criteria:

Consumption Cigarettes and Alcoholic beverages Having Regular Exercise Consumption history Antidepressants

Age

From **25 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple random method was used to determine the sample of each group. First, the names of all patients who entered the study were obtained, assigned to each of the numerical patients, and then a lottery was conducted between them.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

No. 3, Mahyar St., Maulam Blvd., Sari Town

City

Sari

Province

Mazandaran

Postal code

4817875816

Approval date

2019-12-18, 1398/09/27

Ethics committee reference number

IR.MAZUMS.REC.1398.1166

Health conditions studied

1

Description of health condition studied

Fibromyalgia

ICD-10 code

H35.17

ICD-10 code description

fibromyalgia

Primary outcomes

1

Description

Quality of Life

Timepoint

At baseline (before intervention) and 6 weeks after intervention

Method of measurement

Short Form Quality of Life Questionnaire (SF-36)

2

Description

C-reactive-protein

Timepoint

At baseline (before intervention) and 6 weeks after intervention

Method of measurement

By Eliza's research kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Aerobic exercise-placebo group:Aerobic exercise for six weeks (three sessions per week) consisted of 60-70% of maximal heart rate training for 24 to 39 minutes, under the control of a physician.In addition to training, the group took a placebo capsule (30 mg of starch) prepared by Green Plants Company once a day for 6 weeks according to the doctor's instructions.

Category

Treatment - Other

2

Description

Intervention group: Drug Intervention Group: In this group of saffrotin capsules containing standardized dry extract of saffron, made by Green Plants Company, 30 mg once a day was prescribed according to the doctor's instructions for 6 weeks.

Category

Treatment - Other

3

Description

Intervention group: Drug-exercise group (Combined): In addition to aerobic exercise for six weeks (three sessions per week), this group includes exercise with an intensity of 60 to 70% of maximum heart rate for 24 to 39 minutes per session, from Saffrotin capsule containing standardized dry extract of saffron, made by Green Plants Company, Received 30 mg once daily during the intervention as directed by the treating physician.

Category

Treatment - Other

4

Description

Control group: Control group: This group took a placebo capsule (30 mg of starch) prepared by Green Plants Company once a day for 6 weeks according to the doctor's instructions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Sari

Full name of responsible person

Mehri Behzad Khamslo

Street address

Imam Khomeini Hospital., Amir Boulevard., Sari Town

City

Sari

Province

Mazandaran

Postal code

4817875816

Phone

+98 11 3310 9231

Email

mehribehzadkh@gamil.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Seyed Hamzeh

Street address

Imam Khomeini Hospital., Amir Mazandaran St., Sari Town

City

Sari

Province

Mazandaran

Postal code

4817875816

Phone

+98 11 3310 9230

Email

hosseinish20@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

5

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

Mazandaran University of Medical Sciences

Full name of responsible person

Seyed Hamzeh Hosseini

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

Street address

mam Khomeini Hospital., Amir Mazandaran St., Sari Town

City

Sari

Province

Mazandaran

Postal code

4817875816

Phone

+98 11 3310 9231

Email

hosseinish20@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mostafa Behzad Khamslo

Position

Teaching

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 3, Mahyar St., Maulam Blvd., Sari Town

City

Sari

Province

Mazandaran

Postal code

4817875816

Phone

+98 11 3310 9230

Email

mostafabehzadkh@yahoo.com

Web page address

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 3, Mahyar St., Maulam Blvd., Sari Town

City

Sari

Province

Mazandaran

Postal code

4817875816

Phone

+98 11 3310 9230

Email

mostafabehzadkh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mostafa Behzad Khamslo

Position

Teaching

Latest degree