Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Determining the combined effect of MitoQ supplementation and endurance training on cognitive and motor functions, changes in oxidative indices and miR-223 and miR-146a gene expression in postmenopausal and non-menopausal women with multiple sclerosis

Protocol summary

Study aim

Determining the effect of MitoQ and endurance training on cognitive and motor functions, changes in oxidative indices and miR-223 and miR-146a gene expression in postmenopausal and non-menopausal MS women

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 120 patients

Settings and conduct

Subjects in the intervention group: will use 1 capsule of 20 mg of MitoQ supplement every day on an empty stomach for a period of eight weeks, and in the exercise group, they will exercise for eight weeks (30 minutes each session and three times a week) using a Monark bicycle and will be performed at the center of Saman Hojaj. Control group subjects include menopausal and non-menopausal women who do not participate in sports activities and use placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: diagnosis of MS by a neurologist, being in remission، EDSS score less than 6, no acute attacks within 30 Last day. Exclusion criteria: having heart-vascular , liver and kidney diseases, diabetes and any skeletal-muscular disorders .

Intervention groups

1- Menopause, no exercise and no supplement (control) 2- Postmenopausal, without exercise and receiving supplements 3- Menopause, exercise and not receiving supplements 4- Menopause, exercise and receiving supplement 5- Non-menopausal, no exercise, no supplement (control) 6- Non-menopausal, without exercising, receiving supplements 7- Non-menopause, exercise, not receiving supplements 8- Non-menopause, exercise, receiving supplement

Main outcome variables

Serum estrogen level, Serum progesterone level, Serum LH level, Serum FSH level, ROS serum level, TAC serum level, GPx serum level, Serum MDA level, miR-146a gene expression, miR-223 gene expression, Psychological performance measurement, Motor performance measurement Cognitive performance measurement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056558N1**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

Atena Alifarsangi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3341 1372

Email address

alifarsangi.atena@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date
2023-09-06, 1402/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the combined effect of MitoQ supplementation and endurance training on cognitive and motor functions, changes in oxidative indices and miR-223 and miR-146a gene expression in postmenopausal and non-menopausal women with multiple sclerosis

Public title
Determining the combined effect of MitoQ supplementation and endurance training on cognitive and motor functions, changes in oxidative indices and miR-223 and miR-146a gene expression in postmenopausal and non-menopausal women with multiple sclerosis
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of MS by a neurologist Being in remission (at least 2 months after the last relapse) EDSS score less than 6 No acute attacks within 30 Last day Continuing to take MS drugs Not taking medicine for fatigue No taking drugs
Exclusion criteria:
People with cardiovascular, liver and kidney diseases People with diabetes Having any skeletal-muscular disorders and obvious congenital anomalies Having obvious visual impairments Having certain diseases such as cancer People with mental disabilities
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this experimental study, 120 women in the age group between 18 and 65 years old with MS of type RRMS (recurrence and improvement) were randomly selected and divided into eight groups (n=15).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the clinical supervisor and the data analyst were blinded, so that it is not clear which groups will receive the supplement and which groups will receive the placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Afzalipur Hospital., Imam Blvd
City
Kerman
Province
Kerman
Postal code
7616913355
Approval date
2022-10-23, 1401/08/01
Ethics committee reference number
IR.KMU.AH.REC.1401.159

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum estrogen levels
Timepoint
Estrogen hormone will be measured at the beginning of the study (before the intervention) and 60 days (two months) after the start of the supplement and exercise program.
Method of measurement
ELISA KIT

2

Description
Serum progesterone levels
Timepoint

Progesterone hormone will be measured at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

ELISA KIT

3

Description

Serum levels of reactive oxygen species (ROS)

Timepoint

The measurement of ROS will be at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Eliza kit (spectroscopy)

4

Description

serum level of total antioxidant capacity (TAC)

Timepoint

The measurement of TAC will be at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Eliza kit (spectroscopy)

5

Description

Serum level of glutathione peroxidase (GPx)

Timepoint

GPx will be measured at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Eliza kit (spectroscopy)

6

Description

Malondialdehyde (MDA) serum level

Timepoint

The measurement of MDA will be at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Eliza kit (spectroscopy)

7

Description

MicroRNA gene expression (miR-146a)

Timepoint

The measurement of miR-146a will be at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Real time PCR

8

Description

MicroRNA gene expression (miR-223)

Timepoint

The measurement of miR-223 will be at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Real time PCR

9

Description

Measuring psychological function (determining the severity of depression symptoms)

Timepoint

The depression level will be measured at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Beck Depression Questionnaire

10

Description

Measuring psychological function(fatigue)

Timepoint

Fatigue will be measured at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Fatigue Severity Scale Questionnaire (FSS)

11

Description

Measurement of motor function (balance)

Timepoint

The balance measurement will be at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Berg Balance Scale

12

Description

Measuring cognitive performance (memory, attention)

Timepoint

Memory measurement will be at the beginning of the study (before the start of the intervention) and 60 days (two months) after the start of the supplement and exercise program.

Method of measurement

Bicams test

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: non-menopausal women receiving MitoQ supplement. MitoQ supplement is an advanced antioxidant made by MitoQ company in New Zealand. This supplement will be used every morning on an empty stomach with a dose of 20 mg for two months.

Category

Treatment - Other

2

Description

The second intervention group: non-menopausal women receiving MitoQ supplement and exercise program. MitoQ supplement is an advanced antioxidant manufactured by MitoQ Company in New Zealand. This supplement will be used every morning on an empty stomach with a dose of 20 mg for two months. Training sessions: including eight weeks of training (each session 30 minutes and three times a week) will be done by Monark (Leg ergometer) bicycle, the training intensity is based on 65-75% of maximum heart rate and maximum oxygen consumption. VO2Peak) is set. (Each training session will include 5 minutes of warm-up, 20 minutes of main training with training intensity and target heart rate, and 5 minutes of cooling down to 40% of maximum heart rate.).

Category

Treatment - Other

3

Description

The third intervention group: non-menopausal women receiving a placebo and an exercise program. The placebo will be used every morning on an empty stomach for two months. Exercise sessions: including eight weeks of exercise (30 minutes each session and three times a week) by Monark bicycle work meter (Leg ergometer) will be done, the training intensity is adjusted based on 65-75% of maximum heart rate and maximum oxygen consumption (VO2Peak). (Each training session will include 5 minutes of warm-up, 20 minutes of main training with training intensity and target heart rate, and 5 minutes of cooling down to 40% of maximum heart rate.).

Category

Placebo

4

Description

Control group: non-menopausal women without receiving supplements and exercise program

Category

Other

5

Description

The fourth intervention group: menopausal women receiving MitoQ supplement. MitoQ supplement is an advanced antioxidant manufactured by MitoQ Company in New Zealand. This supplement will be used every morning on an empty stomach with a dose of 20 mg for two months.

Category

Treatment - Other

6

Description

The fifth intervention group: menopausal women receiving MitoQ supplement and exercise program. MitoQ supplement is an advanced antioxidant made by MitoQ Company in New Zealand. This supplement will be used every morning on an empty stomach with a dose of 20 mg for two months. Training sessions: including eight weeks of training (each session 30 minutes and three times a week) will be done by Monark bicycle (Leg ergometer), training intensity based on 65-75% of maximum heart rate and maximum oxygen consumption (VO2Peak)) is set. (Each training session will include 5 minutes of warm-up, 20 minutes of main training with training intensity and target heart rate, and 5 minutes of cooling down to 40% of maximum heart rate.).

Category

Treatment - Other

7

Description

The sixth intervention group: menopausal women receiving a placebo and exercise program. The placebo will be used every morning on an empty stomach for two months. Training sessions: including eight weeks of training (30 minutes each session and three times a week) by bicycle. Monark work meter (Leg ergometer) will be done, exercise intensity is adjusted based on 65-75% of maximum heart rate and maximum oxygen consumption (VO2Peak). (Each training session will include 5 minutes of warm-up, 20 minutes of main training with training intensity and target heart rate, and 5 minutes of cooling down to 40% of maximum heart rate.).

Category

Placebo

8

Description

Control group: menopausal women without supplements and exercise program

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Hospital
Full name of responsible person
Atena Alifarsangi
Street address
Shefa St., Islamic Republic Blvd.
City
Kerman
Province
Kerman
Postal code
1151 5- 76187
Phone
+98 34 3211 5786
Email
alifarsangi.atena@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Mohammad Shabani
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Sina Street., Jahad Boulevard., Somaye Crossroad
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Postal code
7619813159
Phone
+98 34 3226 4251
Fax
Email
vcr@kmu.ac.ir
Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Atena Alifarsangi
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Physiology
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person

Atena Alifarsangi

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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
In this study, only information related to the main outcome is accessible

When the data will become available and for how long
Access to information will only be in the form of printed articles

To whom data/document is available
Professors, Doctors (neurologists) and Students

Under which criteria data/document could be used
Access to information will only be in the form of printed articles

From where data/document is obtainable
Access to information will only be in the form of printed articles

What processes are involved for a request to access data/document
Access to information will only be in the form of printed articles

Comments