

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of 6 weeks of Selected Aerobic Exercise and royal jelly use on liver enzymes in patients multiple sclerosis

Protocol summary

Study aim

The purpose of this study is to investigate the effect of 6 weeks of aerobic exercise and oral Royal Jelly on liver enzymes in multiple sclerosis patients.

Design

A clinical trial with a control group, parallel, randomized, with a predicted sample size of 60 and Phase 3 trial

Settings and conduct

This study will be performed on multiple sclerosis patients living in Zahedan, Iran. The duration of the research is 6 weeks and the participants are divided into four groups randomly. Two interventional factors including exercise and Royal jelly are considered for this study.

Participants/Inclusion and exclusion criteria

Acceptance requirements: Multiple sclerosis patients: Expanded Disability Status Scale (EDSS) between 0-4
Non-acceptance requirements: Use of pharmaceutical supplements Cardiovascular disease

Intervention groups

First intervention group: Exercise and Royal jelly; Aerobic exercise and Royal jelly have been selected as interventionists of this group. Second intervention group: Exercise and placebo; Aerobic exercise has been selected as the interventionist of this group. Of course, the placebo will also be used. Third intervention group: Royal jelly. In this group, Royal jelly is an interventionist agent. Control group: Placebo; The placebo will be used in the control group.

Main outcome variables

Aspartate Transaminase changes; Alanine Aminotransferase Changes; Alkaline Phosphatase Changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180612040073N3**

Registration date: **2018-12-14, 1397/09/23**

Registration timing: **retrospective**

Last update: **2018-12-14, 1397/09/23**

Update count: **0**

Registration date

2018-12-14, 1397/09/23

Registrant information

Name

Majid Vahidian-Rezazadeh

Name of organization / entity

University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 6107

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2018-12-02, 1397/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 6 weeks of Selected Aerobic Exercise and royal jelly use on liver enzymes in patients multiple sclerosis

Public title

The effect of exercise and royal jelly on liver enzymes in multiple sclerosis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Multiple sclerosis patients: Expanded Disability Status Scale (EDSS) between 0-4

Exclusion criteria:

Use of pharmaceutical supplements With cardiovascular disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Random unit: Individual

Randomization Tool: Sealed Envelope

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Deputy of research, Zahedan university of medical sciences, Dr Hesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.ZAUMS.REC.1397.218

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Aspartate Transaminase changes

Timepoint

Blood sampling at the beginning of the study (24 hours before the intervention) and 24 hours after the last session of the research protocol

Method of measurement

Blood Sampling

2

Description

Alanine Aminotransferase Changes

Timepoint

Blood sampling at the beginning of the study (24 hours before the intervention) and 24 hours after the last session of the research protocol

Method of measurement

Blood Sampling

3

Description

Alkaline Phosphatase Changes

Timepoint

Blood sampling at the beginning of the study (24 hours before the intervention) and 24 hours after the last session of the research protocol

Method of measurement

Blood Samling

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Exercise and Royal jelly Name of the used substance: Royal Jelly Capsule Chemical composition and concentration: Each capsule contains 1000 mg of Natural Royal Jelly in a base of Soya Oil and Soya Lecithin. Dosage: 1 capsule contains 1000 mg Usage frequency: 1 capsule every morning Duration of use: 42 days (6 weeks) Consumption instruction: Oral

Category

Treatment - Other

2**Description**

Second intervention group: Exercise and placebo Name of the used substance: Placebo Usage frequency: 1 capsule every morning Duration of use: 42 days (6 weeks) Consumption instruction: Oral

Category

Treatment - Other

3**Description**

Third intervention group: Royal jelly Name of the used substance: Royal Jelly Capsule Chemical composition and concentration: Each capsule contains 1000 mg of Natural Royal Jelly in a base of Soya Oil and Soya Lecithin. Dosage: 1 capsule contains 1000 mg Usage frequency: 1 capsule every morning Duration of use: 42 days (6 weeks) Consumption instruction: Oral

Category

Treatment - Other

4**Description**

Control group: Placebo Dosage: 1 capsule contains 1000 mg Usage frequency: 1 capsule every morning Duration of use: 42 days (6 weeks) Consumption instruction: Oral

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Ebn Abitaleb Hospital

Full name of responsible person

Ali Moghtaderi

Street address

Ali Ebn Abitaleb Hospital, Salamat Blvd., Persian Gulf Highway

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of Sistan and Baluchestan

Full name of responsible person

Dor Mohammad Kordi

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Deputy of Research, Central Organization, University of Sistan and Baluchestan, Daneshgah Blvd.

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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

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**

University of Sistan and Baluchestan

Full name of responsible person

Majid Vahidian-Rezazadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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