Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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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moghtaderi@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Sistan and Baluchestan
Full name of responsible person
Dor Mohammad Kordi
Street address
Deputy of Research, Central Organization, University of Sistan and Baluchestan, Daneshgah Blvd.
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Province
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Postal code
9816745845
Phone
+98 54 3113 6246
Email
dor_kordi@yahoo.com
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
Street address
No. 129, Pardisan 1 Ave, University Residential Complex, Daneshgah Blvd
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

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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