Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of 6 weeks aerobic exercise and oral Royal Jelly on TNF-alpha, hs-CRP and neutrophil in multiple sclerosis patients

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 Tumor necrosis factor alpha (TNF-alpha), High-sensitivity C-reactive Protein (hs-CRP) and neutrophils in multiple sclerosis patients.

Design
The clinical trial with a control group, parallel, single-blind, 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. Single-blind blindness will be performed in order to avoid the bias of the subjects and the researcher and the impact on the research results. Two interventional factors including exercise and Royal jelly are considered for this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Multiple sclerosis patients: 'Expanded Disability Status Scale' (EDSS) between 0-4 No use of any supplement Lack of cardiovascular disease Exclusion criteria: Non-MS Patients Multiple sclerosis patients: EDSS more than 4 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
Tumor necrosis factor alpha changes; High-sensitivity C-reactive Protein changes; Neutrophils counts

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180612040073N2**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date
2018-11-30, 1397/09/09

Registrant information

Name
Majid Vahidian-Rezazadeh

Name of organization / entity
University of Sistan and Baluchestan

Country
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
2018-12-01, 1397/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of 6 weeks aerobic exercise and oral Royal Jelly on TNF-alpha, hs-CRP and neutrophil in multiple sclerosis patients

Public title
The effect of exercise and royal jelly on inflammatory factors in multiple sclerosis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Multiple sclerosis patients: Expanded Disability Status Scale (EDSS) between 0-4 Lack of any supplement Lack of cardiovascular disease

Exclusion criteria:
Multiple sclerosis patients: EDSS more than 4 Use of pharmaceutical supplements With cardiovascular disease

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

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)
Single blinded

Blinding description
Participants: The first and second intervention groups will have joint physical activity, but they will be blinded to royal jelly and placebo in the study. The third intervention group and the control group will be blinded to royal jelly and placebo in the study.

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

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743111

Approval date
2018-07-15, 1397/04/24

Ethics committee reference number
IR.ZAUMS.REC.1397.217

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
Tumor necrosis factor alpha 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
"Tumor necrosis factor alpha" test kit

2

Description
High-sensitivity C-reactive Protein 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
"High-sensitivity C-reactive Protein" test kit

3

Description
Neutrophils counts

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
Automatic cell counting machine

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
Treatment - Other

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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Zahedan
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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
Street address
Deputy of Research, Central Organization, University of Sistan and Baluchestan, Daneshgah Blvd.
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9816745845
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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

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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