Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of Royal jelly effect on serum levels of IL-4, TNF- α,TGF-B, IFN-γ cytokines and its antioxidant capacity on Multiple sclerosis patients in comparison with Omega-3

Protocol summary

Study aim
The aim of this study was to compare effects of Royal jelly with Omega 3 on blood factors in multiple sclerosis patients

Design
Clinical trial with control group,Two arm parallel groups randomized double blinded trial. 60 patients with Multiple sclerosis were assigned. For randomization, the permuted block randomization will be used with quadruple blocks, In order to apply the concealment in the randomization process, unique codes will be use on drug boxes.

Settings and conduct
This study will be performed on Multiple sclerosis patients living in Ahvaz, Iran. The duration of the research is 4 weeks and the participants are divided into 2 groups randomly. double-blinding 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 omega-3 and Royal jelly are considered for this study. Before and after treatment, patients give blood test.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Multiple sclerosis patients with fatigue; No other neurological disease; No Diseases like diabetes and autoimmune diseases; No new attack in the last month Exclusion criteria: Pregnancy

Intervention groups
Control group: Interferon (main treatment) with Omega-3 capsules (each capsule contain 1 g from Nature co.) for one month, daily one after breakfast; Intervention group: Interferon (main treatment) with Royal jelly capsules (each capsule contain 1 g from Marnys co.) for one month. one capsule daily after breakfast

Main outcome variables
serum levels of IL-4, TNF- α,TGF-B, IFN-γ cytokines and antioxidant capacity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181026041466N4**
Registration date: **2020-09-16, 1399/06/26**
Registration timing: **retrospective**

Last update: **2020-09-16, 1399/06/26**
Update count: **0**

Registration date
2020-09-16, 1399/06/26

Registrant information

Name
Ali Aghaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3333 8149

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-20, 1398/02/30

Expected recruitment end date
2019-08-21, 1398/05/30

Actual recruitment start date
2019-05-20, 1398/02/30

Actual recruitment end date
2019-08-21, 1398/05/30

Trial completion date
2019-08-21, 1398/05/30

Scientific title
Study of Royal jelly effect on serum levels of IL-4, TNF-α,TGF-B, IFN-γ cytokines and its antioxidant capacity on Multiple sclerosis patients in comparison with Omega-3

Public title
Study of Royal jelly effect on serum levels of cytokines and antioxidant capacity on Multiple sclerosis patients in comparison with Omega-3

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with multiple sclerosis with fatigue No other neurological diseases No new attack in the last month No Diseases like diabetes and autoimmune diseases
Exclusion criteria:
Pregnancy

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com)

Blinding (investigator's opinion)
Double blinded

Blinding description
The allocation sequence will be only known to a person who is not involved in study process; the patients and healthcare providers are all blinded.The aforementioned person will label identical sealed dug boxes as either “group1” or “group2” for each participant .

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Ahvaz University of Medical Sciences, Golestan.
City
Ahvaz
Province
Khouzestan
Postal code
6135733184

Approval date
2020-01-31, 1398/11/11

Ethics committee reference number
IR.AJUMS.REC.1398.825

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
Interferon Gama

Timepoint
first day of tial and one month later

Method of measurement
kits for measuring the Interferon Gama

2

Description
Transforming growth factor beta

Timepoint
first day of tial and one month later

Method of measurement
Measuring kits for measuring the TGF-B

3

Description
Tumor necrosis factor alpha

Timepoint
first day of tial and one month later

Method of measurement
Measuring kits for measuring the TNF-a

4

Description
Interlukin-4

Timepoint
first day of tial and one month later

Method of measurement
Measuring kits for measuring the IL-4

5

Description
antioxidant capacity
Timepoint
first day of tial and one month later
Method of measurement
Frap Test

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Interferon (main treatment) with Omega-3 capsules (1 g daily) for one month. One capsule (made by Nature co) daily after breakfast.
Category
Treatment - Drugs

2

Description
Intervention group: Interferon (main treatment) with Royal jelly capsules (1 g daily) for one month. One capsule (made by Marnys co) daily after breakfast.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital in Ahvaz
Full name of responsible person
Amir Siahpoosh
Street address
Golestan Hospital in Ahvaz, Golestan.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mohamad badavi
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Ahvaz university of medical science, Golestan.
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Aghaei
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Only a part of the data will be shared

When the data will become available and for how long
The access period will be 6 months after the publication of the results

To whom data/document is available
All reaserchers.

Under which criteria data/document could be used
Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable
Applicants can contact with corresponding author by e-mail

What processes are involved for a request to access data/document
Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments