

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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)

Phone

+98 61 3333 8149

Email address

ali.ghaei110@gmail.com

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

Khuzestan

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 trial 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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golestanhospital@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohamad badavi

Street address

Ahvaz university of medical science, Golestan.

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Email

badavi-m@ajums.ac.ir

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

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Alireza Malayeri

Position

Associate professor

Latest degree

Ph.D.

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 researchers.

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