Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of royal jelly consumption on inflammatory mediators including interleukin-1-beta, interleukin-6, interferon-gamma and tumor necrosis factor in patients with multiple sclerosis

Protocol summary

Study aim

Evaluating the effect of royal jelly consumption on the level of inflammatory mediators including interleukin-1-beta, interleukin-6, interferon gamma and tumor necrosis factor in patients with multiple sclerosis.

Design

Division of 60 patients (random and double-blind) into two intervention and control groups, phase 3 trial, 60 half-gram capsules of royal jelly or placebo per patient (60 days), blood sampling at the beginning and after the 60th day, measurement of interleukin 1 beta, tumor necrosis factor alpha, interleukin 6 and interferon gamma and EDSS after intervention.

Settings and conduct

This study is conducted in Dezful University of Medical Sciences. 60 MS patients in two groups, case and control, before and after blood sampling and their inflammatory cytokine levels are measured.

Participants/Inclusion and exclusion criteria

MS Patients who have been diagnosed with the disease based on neurological examinations and imaging by a neurologist, and their disease subtype is relapsing, improving or secondary progressive, and have been treated with interferon drugs and have at least six A month has passed since the start of their drug treatment, they are included in the study Criteria for non-entry 1. Patients suffering from anemia, chronic heart diseases, lung diseases, diabetes, autoimmune diseases such as rheumatoid arthritis, SLE, suffering from liver diseases, patients who are being treated with immunosuppressive drugs. History of asthma and allergy in the patient.

Intervention groups

60 patients were randomly divided into two intervention and control groups in a double-blind manner, and 60 half-gram capsules of royal jelly or placebo were delivered to each patient to consume one capsule daily before a meal.

Main outcome variables

IL-6,TNF-α ,IFN-γ IL-1β and EDSS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221002056071N1**
Registration date: **2022-12-29, 1401/10/08**
Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**
Update count: **0**

Registration date

2022-12-29, 1401/10/08

Registrant information

Name

mahin behzadifard

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of royal jelly consumption on inflammatory mediators including interleukin-1-beta, interleukin-6, interferon-gamma and tumor necrosis factor in patients with multiple sclerosis

Public title

The effect of royal jelly on inflammatory mediators in multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria of participants:: Patients' subtype of M.S should be the "relapsing-remitting MS" (RRMS). The patient's age should be 20- 45 years old and all of them treated with interferon for at least 6 months.

Exclusion criteria:

Patients with anemia, chronic heart disease, lung disease, diabetic Mellitus, autoimmune diseases such as rheumatoid arthritis, SLE, liver diseases, and a history of asthma and allergies. Patients are treated with corticosteroids or ACTH drugs, or consumption of supplements.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization method will be used and randomization unit is individual. According to the sample size of 60 and two treatment groups, 10 blocks with volume 6 are prepared, for this, a list of six combinations of Royal Jelly and placebo is prepared and randomly allocated each compound to one block. In order to reduce the prediction rate, the therapist is not aware of the permutation block method and especially the size of the block.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding in this study means that the patient does not know whether he is taking a placebo or a capsule containing royal jelly. The appearance of the capsules is the same, and the researcher who gives the capsules to the two groups is completely unaware of whether they are placebo or contain gel. Even numbers of capsules containing gel are given to patients with odd numbers of placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National Committe for Ethics in Biomedical research

Street address

Azadegan

City

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Khouzestan

Postal code

1930429878

Approval date

2022-11-01, 1401/08/10

Ethics committee reference number

IR.DUMS.REC.1401.076

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35-G37

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Expanded Disability Status Scale

Timepoint

Study of "Expanded Disability Status Scale" at the beginning of the study and on day 60 after the use of Royal Jelly

Method of measurement

Scoring from zero (best condition) to 10 (death due to MS) according to the neurologist

Secondary outcomes

1

Description
The amount of change in the amount of inflammatory cytokines
Timepoint
Investigating the level of inflammatory cytokines at the beginning of the study and on the 60th day after the end of using royal jelly
Method of measurement
Eliza method

Intervention groups

1

Description
Intervention group:The case group (30 MS patients) received sixty 500mg capsules of royal jelly prepared by Rodin Food Industry Company and they were asked to eat one capsule daily before one of their meals.
Category
Treatment - Drugs

2

Description
30 MS patients as case group received sixty capsules contained 500g Royal jelly) which were prepared from Rodin Food Industry Company and they were asked to eat one capsule daily before one of the meals. .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ganjovian Hospital
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Sponsors / Funding sources

1

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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
Dezfoul 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
Dezfoul University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is a plan to release it

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available