Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of protective effect of Royal Jelly on Serum Oxidative Stress markers and Interleukin-1Beta of Patients with Multiple Sclerosis.

Protocol summary

Study aim
The evaluation of the protective effect of Royal Jelly capsule consumption on serum oxidative stress markers and level of Interleukin-1 beta of patients with Multiple sclerosis.

Design
Dividing 60 patients (random and double-blind) into intervention and control groups, phase 3 trial, 45 half-gram capsules of Royal Jelly or placebo to the patient (45 days), blood sampling at the beginning and after the 45th day, assessment (MDA, SOD, GPx, IL-1) and EDSS after the intervention.

Settings and conduct
In Dezful University of Medical Sciences: Determining the EDSS level of patients by a neurologist, dividing 60 patients (random and double-blind) into two intervention and control groups, 45 half-gram capsules of Royal Jelly or placebo per patient (daily consumption of one), then blood sampling at the beginning and after the day 45th, measurement of MDA, SOD, GPx, catalase and IL-1, and EDSS after the intervention.

Participants/Inclusion and exclusion 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. conditions for not entering the study: The 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.

Intervention groups
Dividing 60 patients (random and double-blind) into intervention and control groups, 45 half-gram capsules of Royal Jelly or placebo to each patient (daily consumption of one).

Main outcome variables
Decreased MDA, IL1؛ Increased SOD, GPx, CAT؛ improved EDSS in intervention groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220116053732N1**
Registration date: **2022-05-08, 1401/02/18**
Registration timing: **retrospective**

Last update: **2022-05-08, 1401/02/18**
Update count: **0**

Registration date
2022-05-08, 1401/02/18

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2022-04-04, 1401/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of protective effect of Royal Jelly on Serum Oxidative Stress markers and Interleukin-1Beta of Patients with Multiple Sclerosis.

Public title
Evaluation of protective effect of Royal Jelly on Serum Oxidative Stress markers and Interleukin-1 Beta of Patients with Multiple Sclerosis.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of patients should be 20-45 The sub type of M.S should be "Relapsing-Remitting MS" (RRMS). The diagnosis of "RRMS" is confirmed by a neurologist based on neurological examination and imaging. Patients should be 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, ... Patients treated with corticosteroids or ACTH. Use of any supplements by patients. History of asthma and allergies in the patient. Occurrence of allergic symptoms during the study Occurrence of a "MS" attack during the study period. The patient' s refuse to continue study.

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
Patients were invited to participate in the study and after obtaining informed consent, they were blindly classified into control or intervention groups. The clinician, researcher, outcome evaluator, and data analyst all play their role blindly.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Dezful University of Medical Sciences

Street address
Azadegan boulevard, deputy of training, school of medicine, Dezful, Iran.

City
Dezful

Province
Khouzestan

Postal code
6461665145

Approval date
2020-09-28, 1399/07/07

Ethics committee reference number
IR.DUMS.REC.1399.038

Health conditions studied

1

Description of health condition studied
MS disease

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis (of):NOS brain stem cord disseminated generalized

Primary outcomes

1

Description
The rate of change of oxidative stress state

Timepoint
Evaluation of "oxidative stress status" at the beginning of the study and on day 30 after the use of Royal Jelly

Method of measurement
The assay of Malondialdehyde , Superoxide dismutase, Catalase, Nitric oxide

Secondary outcomes

1

Description
Expanded Disability Status Scale
Timepoint
Study of "Expanded Disability Status Scale" at the beginning of the study and on day 30 after the use of Royal Jelly
Method of measurement
Scoring from zero (best condition) to 10 (death due to MS) according to the neurologist

Intervention groups

1

Description
The intervention group included people with MS who on the first day of the study and on the 50th day of the study "after swallowing a capsule containing 350 mg of royal jelly lyophilized daily", "Extensive disability status scale" and blood sampling to assess the status of "oxidative stress "It will be measured. The study of oxidative stress is done by measuring factors such as malondialdehyde, catalase, superoxide dismutase and nitric oxide.
Category
Treatment - Drugs

2

Description
Control group included people with MS who on the first day of the study and on the 50th day of the study "after swallowing a capsule containing 350 mg of wheat flour daily", "Extensive disability status scale" and blood sampling to assess the status of "oxidative stress "It will be measured. The study of oxidative stress is done by measuring factors such as malondialdehyde, catalase, superoxide dismutase and nitric oxide.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neshat Clinic 2
Full name of responsible person
Dr. Mohammad Reza Zandi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dezfoul University of Medical Sciences
Full name of responsible person
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No. 107, School of Paramedical, Dezful University of Medical Sciences, next to the Traffic Department, Azadegan Blvd, Dezful.
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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)
Yes - There is a plan to make this available
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
Title and more details about the data/document
No
When the data will become available and for how long
No
To whom data/document is available
No
Under which criteria data/document could be used
No
From where data/document is obtainable
No
What processes are involved for a request to access data/document
No
Comments