Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Roy Jelly on quality of life and health status of multiple sclerosis patients

Protocol summary

Study aim
Determin the effect of Roy Jelly on quality of life and health status of multiple sclerosis patients

Design
The present study is a randomized interventional study will be performed on two groups of 100 patients.

Settings and conduct
A study will be conducted on 100 MS patients referring to Hamadan MS Center. In the intervention group, a 500-mg capsule of royal jelly daily is given for one day for 75 days and in a daily control group one placebo for 75 days. Both groups receive the usual treatment according to expert advice. Demographic information will be completed by the researcher at the time the patient enters the department. Quality of life indicators and patient's level of health are completed once before the intervention stage and then 75 days after the intervention using the questionnaire by the researcher. Controls in the control group will not be performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age is between 18 and 60 years old, Confirm Diagnosis of MS by the neurologist, Have complete and informed consent to participate in the study Exclusion criteria: Unwillingness to continue participating in the study, Patient death

Intervention groups
In the intervention group, a 500-mg capsule of royal jelly daily is given for one day for 75 days and in a daily control group one placebo for 75 days. Both groups receive the usual treatment according to expert advice. Demographic information will be completed by the researcher at the time the patient enters the department. Quality of life indicators and patients' health level are completed once before the intervention stage and then 75 days after the intervention using the questionnaire by the researcher.

Main outcome variables
quality of life and health status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160110025929N13**
Registration date: **2018-06-02, 1397/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-02, 1397/03/12**
Update count: **0**

Registration date
2018-06-02, 1397/03/12

Registrant information

Name
Mehdi Molavi Vardanjani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3422 5056

Email address
m.molavi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-31, 1397/03/10

Expected recruitment end date
2019-05-31, 1398/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Roy Jelly on quality of life and health status of multiple sclerosis patients

Public title
The effect of Roy Jelly on quality of life and health status
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age is between 18 and 60 years Have complete and informed consent to participate in the study Confirm Diagnosis of MS by the neurologist
Exclusion criteria:
Patient death Unwillingness to continue participating in the study
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
100 patients will be selected as available, then using random blocking method, two groups of intervention (Royal) and control group will be placed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan
City
Hamadan
Province
Hamadan
Postal code
38698-65178
Approval date
2018-05-19, 1397/02/29
Ethics committee reference number
IR.UMSHA.REC.1397.96

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
Quality of Life
Timepoint
Before and after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
health status
Timepoint
Before and after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: In the intervention group, a 500 mg capsule daily jelly gel containing substances such as 10-hydroxy-2-decenoic acid, B group vitamins, potassium, calcium, magnesium, zinc, iron, and copper, a number for 75 The day will be used by a neurologist. Demographic information will be completed by the researcher at the time the patient enters the department. The quality of life indicators and the level of health of the patients are completed once before the intervention stage and then 75 days after the intervention using the questionnaire by the researcher.
Category
Rehabilitation

2

Description
Control group: Except for routine medication and care,

no special action will be taken.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Khodayar oshvandi

Street address

Besat St, Besat hospital, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

oshvandi2005@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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s-bashirian@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Khodayar oshvandi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

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Person responsible for updating data

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Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mehdi Molavi Vardnjani

Position
instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Email

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