Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Oct 2023

The effects of royal jelly supplementation on inflammatory status, oxidative stress, mental health, cognitive function, disease severity and quality of life in patients with ischemic stroke

Protocol summary

Study aim

Evaluation of the effect of Royal Jelly supplementation on inflammatory status, oxidative stress, mental health, cognitive function, disease severity, and quality of life in patients with ischemic stroke

Design

A parallel randomized triple-blind placebo-controlled clinical trial

Settings and conduct

Participants will be selected from patients with ischemic stroke referred to Al-Zahra Hospital. By reviewing the patient file, individuals will be evaluated based on the inclusion criteria and individuals who meet the conditions to participate in the study will be included in the study. The intervention group will receive one tablet of Royal Jelly (containing 1000 mg of Royal Jelly powder) daily after breakfast and the control group will receive one placebo daily, which is similar in shape, color, taste, and smell. Patients, researchers, and those performing statistical analysis are not aware of how randomly assigned individuals are.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of ischemic stroke, age 45-80 years, no other diseases such as acute kidney, liver, heart, other neurological diseases, malignancies, asthma, allergies and dermatitis Exclusion criteria: Unwillingness of people to continue the study for any reason, adherence less than 80%, recurrence of stroke

Intervention groups

Intervention group: The intervention group will receive one tablet of Royal Jelly (containing 1000 mg of Royal Jelly powder) daily after breakfast. Control group: The control group will receive one placebo daily which is similar to Royal Jelly supplement in terms of shape, color, taste and smell.

Main outcome variables

The aim of this study was to evaluate the effect of Royal Jelly supplementation on inflammatory status, oxidative stress, mental health, cognitive function, disease severity, and quality of life in patients with ischemic stroke.

General information

Reason for update

Alteration of sample size calculation formula

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040827N4**
Registration date: **2021-10-16, 1400/07/24**
Registration timing: **prospective**

Last update: **2022-08-02, 1401/05/11**
Update count: **1**

Registration date

2021-10-16, 1400/07/24

Registrant information

Name

Reza Amnai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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r_amani@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of royal jelly supplementation on inflammatory status, oxidative stress, mental health, cognitive function, disease severity and quality of life in patients with ischemic stroke

Public title
Effect of royal jelly in treatment of stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of ischemic stroke by a neurologist NIHSS score of 5-20 An absence of previous stroke or or MRS score of ≤ 1 for those with previous stroke Ischemic stroke of non-brain stem area age of 45-80 Not following specific dietary regimen in previous 3 months Not taking multivitamins and antioxidant supplements in the previous 3 months Non pregnant and lactating women No other diseases such as acute kidney, liver, heart, other neurological diseases, malignancies, no asthma, allergies and dermatitis Not suffering from mental retardation (mental disabilities) Not taking drugs that interfere with Royal Jelly supplementation (warfarin) Lack of sensitivity and allergy to honey and its products
Exclusion criteria:
Unwillingness to continue the study for any reason Adherence of less than 80% to the intervention (taking less than 80% of Royal Jelly supplement that should be taken during the 12 weeks of the intervention will be considered low adherence) Recurrence of stroke Death Use of antioxidant and multivitamin supplements during the study Prescription of warfarin during the study Gastrointestinal side effects or allergies caused by taking Royal Jelly supplement Diagnosis of other diseases such as kidney, autoimmune and malignancies during the study
Age
From **45 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed by permuted block randomization method using size 6 blocks by Stata statistical software version 16. To conceal the random assignment process, 10-digit random codes are written on 64 paper labels without a specific order and framework, which is the relevant treatment identification number, and only one person outside the design will be aware of the code. Labels will be affixed to drug packages in a random order list.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Drugs and placebo are given to both groups in completely identical, unlabeled containers, which are prepared and coded in the same color and odor, by random allocation by the design partner, so neither patient is aware of the specific treatment and will not be informed until the end of the study. Also, the researcher evaluating the desired outcomes is unaware of the random allocation process and the type of treatment performed. In order to analyze the data, a statistician and epidemiologist who is separate from the study process and is unaware of all the processes performed will be used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjrib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-10-09, 1400/07/17
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.291

Health conditions studied

1

Description of health condition studied
Ischemic stroke

ICD-10 code
G46.4
ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
Superoxide dismutase
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

2

Description
Glutathione peroxidase
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

3

Description
Malonaldehyde
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

4

Description
Total antioxidant capacity
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

5

Description
Total oxidant status
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

6

Description
Nitric oxide
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

7

Description
Brain derived neurotrophic factor
Timepoint
At baseline and after 12 weeks
Method of measurement
ELISA method

8

Description
Modified Rankin Scale
Timepoint
At baseline and after 12 weeks
Method of measurement
Questionnaire

9

Description
Stroke specific quality of life
Timepoint
At baseline and after 12 weeks
Method of measurement
Questionnaire

10

Description
Cognitive function
Timepoint
At baseline and after 12 weeks
Method of measurement
MMSE questionnaire

11

Description
Fatigue score
Timepoint
At baseline and after 12 weeks
Method of measurement
FSS questionnaire

12

Description
Uric acid
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetry

13

Description
C-reactive protein
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetry

14

Description
Erythrocyte sedimentation rate
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetry

15

Description
Blood pressure
Timepoint
At baseline and after 12 weeks
Method of measurement
sphygmomanometer

16

Description
Lipid profile
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetry

17

Description
Fasting Blood Glucose
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetry

Secondary outcomes

1

Description
Stress score
Timepoint
At baseline and after 12 weeks
Method of measurement
DASS-21 questionnaire

2

Description
Depression score
Timepoint
At baseline and after 12 weeks
Method of measurement
DASS-21 questionnaire

3

Description
Anxiety score
Timepoint
At baseline and after 12 weeks
Method of measurement
DASS-21 questionnaire

4

Description
Appetite score
Timepoint
At baseline and after 12 weeks
Method of measurement
SNAQ questionnaire

5

Description
Mid arm circumference
Timepoint
At baseline and after 12 weeks
Method of measurement
Tape meter

Intervention groups

1

Description
Intervention group: The intervention group will receive one tablet of Royal Jelly (containing 1000 mg of Royal Jelly powder) daily after breakfast for 12 weeks. Royal Jelly supplement will be provided by Koozeh Asal Aria Company (Iran-Isfahan).
Category
Rehabilitation

2

Description
Control group: The control group will receive a placebo daily supplement that is similar in shape, color, taste, and smell to the supplement. The placebo will be provided by Koozeh Asal Aria Company (Iran-Isfahan).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Reza Amani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reza Amnai
Position
Professor
Latest degree
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Other areas of specialty/work
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
A major part of the information will be available for the population
When the data will become available and for how long
12 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
To conduct similar studies
From where data/document is obtainable
Reza Amani
What processes are involved for a request to access data/document
The data will be sent as soon as possible after receiving the request
Comments