

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)

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Email address

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

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Isfahan

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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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
Ph.D.

Other areas of specialty/work
Nutrition

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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