Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of oral consumption of Royal jelly on menopausal symptoms in 45-60 years old menopausal women

Protocol summary

Study aim
To determine the effectiveness of royal jelly supplements on menopausal symptoms

Design
Clinical trials with drug and placebo control group, treatment-based, with parallel groups, blind, randomized by block

Settings and conduct
A clinical trial study on women with menopausal symptoms referred to gynecological clinics of Khaleej-e-fars Hospital in Bandar Abbas. Participants will randomly divided into two groups. One group receive Royal jelly and the other group will receive placebo. All participants are blinded to type of treatment. Two months later, menopausal symptoms will be evaluated by Menopausal Rating Scale.

Participants/Inclusion and exclusion criteria
Women with menopausal symptoms who were referred to gynecological clinics of Khaleej-e-fars Hospital in Bandar Abbas

Intervention groups
Participants will randomly divided into 2 groups A and B. To group A, royal jelly supplementation is provided from Nature Life factory manufactured in Canada with a dose of 1000 miligram everydayfor8 weeks. Group B are given a placebo.

Main outcome variables
Menopausal symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181107041585N1**
Registration date: **2019-02-01, 1397/11/12**
Registration timing: **prospective**
Last update: **2019-02-01, 1397/11/12**
Update count: **0**

Registration date
2019-02-01, 1397/11/12

Registrant information

Name
Fatemeh Darsareh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 76 3355 4515

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famadarsareh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-09, 1397/11/20

Expected recruitment end date
2019-05-10, 1398/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oral consumption of Royal jelly on menopausal symptoms in 45-60 years old menopausal women

Public title
Effect of oral consumption of Royal jelly on menopausal symptoms

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 45 and 60 years old; Married; 12 months amenorrhea; Normal pap smear in past12 months Normal finding in physical examinations

Exclusion criteria:

serious chronic medical conditions Allergy to honey

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

all eligible participants before intervention were randomly divided into two groups using a block randomization procedure

Blinding (investigator's opinion)

Double blinded

Blinding description

Blindness will be that the supplementation of royal jelly and placebo will not be communicated to anyone by someone outside the research team and team members such as a clinical care provider, and supplementary participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bandar Abbas University of Medical Sciences

Street address

Ethics Committee of Bandar Abbas University of Medical Sciences

City

Bandar abbas

Province

Hormozgan

Postal code

7919783141

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

970149

Health conditions studied

1

Description of health condition studied

Menopausal symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Menopausal symptoms score

Timepoint

End of second month of intervention

Method of measurement

Menopausal Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receivedroyal jelly 1000 miligram every day for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: consumption of placebo every day for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khaleej fars hospital

Full name of responsible person

Fatemeh Darsareh

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Sponsors / Funding sources

1

Sponsor
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
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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