

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of oral Royal jelly on menopausal symptoms and sexual function in 50-60 years old menopausal women

Protocol summary

Summary

The objective of this study is to assess effect of oral Royal jelly on menopausal symptoms and sexual function in 50-60 years old menopausal women referred to selected health centers related to Iran University of Medical Sciences 2013- 2014. In a triple- blind, placebo-controlled trial, 110 menopausal aged 50-60 years, will be recruited and fill "Sabbatsberg Sexual Rating Scale (SSRS), Menopause Rating Scale (MRS) and personal characteristics" questionnaire, and will sign an Informed Consent from. Inclusion criteria: Not having physical and psychological diseases in women and their spouses, having coitus at least twice in a month, Not using of sedative and hypnotic drugs, HRT and herbal medicines more than once a week, Not allergic to honey consumption and BMI less than 28 kg m . Exclusion criteria: Not having sexual activity during the study, not using the drug under investigation for more than 6 days in a month, using of any hormonal and herbal medication, using of Soy more than one meal per week, starting any vegetarian diet and allergic and not using of Antibiotics or Antacids during the study. The participants will be randomly divided in intervention and control groups (55 women in each group). The intervention group will receive Royal Jelly, 100 mg capsule, once daily for two months and the control group will receive placebo capsule, at the same dose as the intervention group. After two months, Sabbatsberg Sexual Rating Scale and Menopause Rating Scale Scores will be measured again, compared and analyzed in the two groups before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306022172N14**

Registration date: **2013-06-12, 1392/03/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Simin Taavoni

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 8161

Email address

staavoni@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Institute for Islamic & Complementary Medicine

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral Royal jelly on menopausal symptoms and sexual function in 50-60 years old menopausal women

Public title

Effect of oral Royal jelly on menopausal symptoms and sexual function

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Not having physical and psychological diseases in women and their spouses, having coitus at least twice in a month, Not using of sedative and hypnotic drugs, HRT and herbal medicines more than once a week, Not allergic to honey consumption and BMI less than 28 kg m . Exclusion criteria: Not having sexual activity during the study, not using the drug under investigation for more than 6 days in a month, using of any hormonal and herbal medication, using of Soy more than one meal per week, starting any vegetarian diet and allergic and not using of Antibiotics or Antacids during the study.

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute for Islamic & Complementary
Medicine

Street address

No.9, Pirniya1, Ave-Northern Lalehzar, street
Jomhoory eslami,Tehran

City

Tehran

Postal code

Approval date

2013-05-29, 1392/03/08

Ethics committee reference number

ط م/26/پ 122

Health conditions studied

1

Description of health condition studied

sexual disfunctions , menopause symptoms, Symptoms of Menopause

ICD-10 code

F52.8, F52

ICD-10 code description

Other sexual dysfunction, not caused by organic disorder or disease,

Primary outcomes

1

Description

Menopausal symptoms score

Timepoint

End of first month of intervention

Method of measurement

Menopause Rating Scale (MRS) questionnaire

2

Description

Sexual function score

Timepoint

End of first month of intervention

Method of measurement

sabbastberg sexual function questionnaire

Secondary outcomes

1

Description

Sexual function score

Timepoint

End of first and second month of intervention

Method of measurement

sabbastberg sexual function questionnaire

2

Description

Menopausal symptoms score

Timepoint

End of first and second month of intervention

Method of measurement

Menopause Rating Scale (MRS) questionnaire

Intervention groups

1

Description

Intervention group: Royal Jelly Capsules, 100 Mg capsules once daily in tow month.

Category

Treatment - Other

2

Description

Control group: Placebo Capsules, 100 Mg capsules once daily in tow month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Abouzar Clinic

Full name of responsible person

Bahareh Lesani

Street address

Dastgheib Street, Ostad Moeen Street

City

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2

Recruitment center

Name of recruitment center

Fazel Haelth and Cure Center

Full name of responsible person

Dr Katyoon Seif Farahi

Street address

Water Street, Abdolazadeh Street, Keshavarz
Bulvard, Valiaasr Square

City

Tehran

3

Recruitment center

Name of recruitment center

Shahid Ghafari Haelth and Cure Center

Full name of responsible person

Dr Zahra Malayeri

Street address

Bazargolha, Phase 2, Ekbatan Parish

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic & Complementary
Medicine

Full name of responsible person

Dr. Ashrafedin Gooshegir

Street address

No.9, Pirniya1, Ave-Northern Lalehzar, street
Jomhoory eslami,Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Institute for Islamic & Complementary Medicine

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing and Midwifery Faculty, tehran University of
Medical Sciences

Full name of responsible person

simin Taavoni

Position

PhD in Medical Education, M.Sc in Medical Education,
M.Sc in Midwifery Education, Academic Faculty

Other areas of specialty/work

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Contact

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Full name of responsible person
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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty