Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity
Iran University of Medical Sciences
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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
122/پ26/م ط

Health conditions studied

1

Description of health condition studied
sexual disfunctions , menopause symptems, 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
Tehran

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, Abdolahzadeh 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
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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