effect of oral Royal jelly on severity of premenstrual syndrome in students living in Tehran medical university dorms

Protocol summary

Summary
This triple-blind randomized clinical trial will be conducted to assess the effect of Royal jelly on premenstrual symptoms. The study population comprise 110 female students who live in Tehran University of Medical Sciences dorms, having premenstrual symptoms according to premenstrual profile 2005 and satisfied the inclusion criteria such as no allergy to products of honey and not using any kind of treatment that influence the premenstrual syndrome. The participants will be randomly assigned into Royal jelly or placebo group. The participants in the intervention group will receive royal jelly capsule while participants in the control group will receive placebo with the same dosage. The outcome measures in this study are premenstrual symptoms, as obtained through the premenstrual profile 2005 before and during the intervention. At the end of the study, two premenstrual syndrome sign scores will be obtained for every participant (1 before intervention to recognize the eligible samples and 1, after 2 cycle intervention).

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201107192172N12
Registration date: 2011-12-10, 1390/09/19
Registration timing: registered_while_recruiting

Last update:
Update count: 0
Registration date
2011-12-10, 1390/09/19

Registrant information
Name
Simin Taavoni
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research, Tehran University of Medical Sciences and Research Institute for Islamic & Complementary Medicine

Expected recruitment start date
2011-08-23, 1390/06/01
Expected recruitment end date
2012-01-21, 1390/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
effect of oral Royal jelly on severity of premenstrual syndrome in students living in Tehran medical university dorms

Public title
Effect of oral Royal jelly on severity of premenstrual syndrome

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: age between 20 and 35 years old; not taking any medicine; having symptoms in 2 past cycles; not taking any complements; no allergy to honey or Royal jelly; no changes in diet & exercise program; not smoking, alcohol or drug usage
Exclusion criteria: use of
any kind of drug or therapy for symptom relief during the study intervention; side effects during intervention for example allergy; change in diet or physical exercise program during the study; any kind of crisis in participant or her family; not taking royale jelly or placebo more than 7 days in 2 cycles

**Age**
- From **20 years** old to **35 years** old

**Gender**
- Female

**Phase**
- 1

**Groups that have been masked**
- No information

**Sample size**
- Target sample size: **110**

**Randomization (investigator's opinion)**
- Randomized

**Randomization description**
- Triple blinded

**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: Tehran University of Medical Sciences Department
  - Street address: No 23, Dameshgh St., Valiasr Ave
  - City: Tehran
  - Postal code: 1390/09/12
  - Approval date: 2011-12-03
  - Ethics committee reference number: 14628

**Health conditions studied**

**1**
- **Description of health condition studied**
  - Premenstrual syndrome
- **ICD-10 code**
  - N94.3
- **ICD-10 code description**
  - Premenstrual tension syndrome

**Primary outcomes**

**1**
- **Description**
  - Premenstrual syndrome (screening)
- **Timepoint**
  - 2 menstrual cycles
- **Method of measurement**
  - premenstrual profile 2005 scale

**Secondary outcomes**

**1**
- **Description**
  - Premenstrual syndrome (prevention)
- **Timepoint**
  - during intervention for 2 cycles
- **Method of measurement**
  - premenstrual profile 2005 scale

**Intervention groups**

**1**
- **Description**
  - Oral administration of 1000 mg Royal jelly capsule for 2 menstrual cycle
- **Category**
  - Prevention

**2**
- **Description**
  - placebo
- **Category**
  - Placebo

**Recruitment centers**

**1**
- **Recruitment center**
  - Name of recruitment center: Amol dorm
  - Full name of responsible person: Miss Ahmadi
  - Street address: No: 138, Amol St., Shareati Ave.
  - City: Tehran

**2**
- **Recruitment center**
  - Name of recruitment center: Motahari dorm
  - Full name of responsible person: Miss Honar khah
  - Street address: No: 39, Eftekhar Alley, Larestan St., Motahari Ave.
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Esmat Karimie
Street address
No 23, Dameshgh St., Valiasr Ave, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
empty
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
Type of organization providing the funding
empty

2
Sponsor
Name of organization / entity
Research Institute for Islamic & Complementary Medicine
Full name of responsible person
Abdollahi
Street address
No9, pirnia 1 alley, north lalezar st, jomhoori islamii blvd, Tehran, Iran
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
empty
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
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
M.Sc in Medical Education, M.Sc in Midwifery Education, Faculty Member & Researcher
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**Full name of responsible person**
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**Other areas of specialty/work**

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**Email**

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**Web page address**

**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