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

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 supplements; 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**
Blind

**Blinding (investigator's opinion)**
Triple blind

**Blinding description**
Placebo

**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.
### Sponsors / Funding sources

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<td><strong>Sponsor</strong></td>
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<tr>
<td><strong>Name of organization / entity</strong></td>
<td>Vice chancellor for research, Tehran University of Medical Sciences</td>
</tr>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Esmat Karimie</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td>No 23, Dameshgh St., Valiasr Ave, Tehran, Iran</td>
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<tr>
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<td><strong>Name of organization / entity</strong></td>
<td>Research Institute for Islamic &amp; Complementary Medicine</td>
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<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Abdollahi</td>
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<tr>
<td><strong>Street address</strong></td>
<td>No9, pirmia 1 alley, north lalezar st, jomhoori islami blvd, Tehran, Iran</td>
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### Person responsible for general inquiries

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<tr>
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<td>Nursing and Midwifery Faculty, Tehran University of Medical Sciences</td>
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<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Simin Taavoni</td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td>M.Sc in Medical Education, M.Sc in Midwifery Education, Faculty Member &amp; Researcher</td>
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### Person responsible for scientific inquiries

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### Person responsible for updating data

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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

Other areas of specialty/work

Street address
3rd Floor, No.12, Nadjmabady St. Kazeroon St. Mirdamad Ave

City
Tehran

Postal code
1919915375

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
eempty

Statistical Analysis Plan
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Informed Consent Form
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Clinical Study Report
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Analytic Code
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Data Dictionary
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