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

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

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, 1390/09/12
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

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

### 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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  - **City**: Tehran
- **Postal code**: 1919915375
- **Phone**: +98 21 6692 1228
- **Email**: staavoni14@yahoo.com
- **Web page address**: empty

### Person responsible for scientific inquiries

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- **Email**: staavoni14@yahoo.com
- **Web page address**: empty

### Person responsible for updating data

**Contact**
- **Name of organization / entity**: empty
Nursing and Midwifery Faculty, Tehran University of Medical Sciences

**Full name of responsible person**
Simin Taavoni

**Position**
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**Other areas of specialty/work**

**Street address**
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**City**
Tehran

**Postal code**
1919915375

**Phone**

**Fax**

**Email**

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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