

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8820 8161

##### Email address

staavoni@iums.ac.ir

##### 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

#### 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

#### 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, Eftekhari 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

#### 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*

### 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 laleazar st, jomhoori islami  
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

#### 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**  
M.Sc in Medical Education, M.Sc in Midwifery  
Education, Faculty Member & Resaercher

#### Other areas of specialty/work

**Street address**  
3rd Floor, No.12, Nadjmabady St. Kazeroon St.  
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**City**  
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**Postal code**  
1919915375

**Phone**  
+98 21 6692 1228

#### Fax

**Email**  
staavoni14@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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Nursing and Midwifery Faculty, Tehran University of  
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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*