

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

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Person responsible for updating data

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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