Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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

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
premenstural 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
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 lalezar 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
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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