Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Sep 2026

Evaluating the effect of Rosaceous Sinensis on the severity of dysmenorrhea in subjects with primary dysmenorrhea

Protocol summary

Summary

This double blind clinical trial will be performed on 110 female students of Hamedan University of Medical Sciences. Subjects with inclusion criteria: 18-24 years of age; regular menstrual periods with 21-35 day cycles and 3-10 days bleeding period; no identified physical and Pelvic diseases and exclusion criteria: taking 20 drop of Rosaceous or less on two consecutive days; allergy to Rosaceous during intervention, will be divided into two groups of 55 subjects randomly and will use 10 drops of Rosaceous sinensis or placebo two times a day during first three days of menstrual period for two consecutive months. Pain intensity will be measured by a visual analogue scale three times a day and a four-point verbal rating scale will be employed to evaluate systemic symptoms. The present study examines the effect of Rosaceous on the severity and systemic symptoms of primary dysmenorrhea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311216807N10**
Registration date: **2014-11-05, 1393/08/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-05, 1393/08/14

Registrant information

Name
Sedigheh Amir Ali Akbari
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Iran (Islamic Republic of)
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+98 21 2272 9240
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akbarisedd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-06-16, 1393/03/26

Expected recruitment end date

2014-10-18, 1393/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Rosaceous Sinensis on the severity of dysmenorrhea in subjects with primary dysmenorrhea

Public title

Effect of Rosaceous Sinensis on primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-24 years of age; regular menstrual periods with 21-35 days cycles and 3-10 days bleeding period; no identified physical and Pelvic diseases.
Exclusion criteria: taking 20 drop of Rosaceous or less on two consecutive days; allergy to Rosaceous during intervention.

Age

From **18 years** old to **24 years** old

Gender

Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences and health services
Street address
Shahid Beheshti University of Medical Sciences, Velenjak Street, Shahid Chamran High Way, Tehran, Iran
City
Tehran
Postal code
1985717443
Approval date
2014-06-16, 1393/03/26
Ethics committee reference number
1393-1-86-12862-1

Health conditions studied

1

Description of health condition studied
Dysmenorrhea
ICD-10 code
N94.4
ICD-10 code description
Primary Dysmenorrhea

Primary outcomes

1

Description
Intensity of pain
Timepoint
Eight weeks before treatment, Eight weeks after treatment
Method of measurement
Macgill pain scaling

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Control group: Water and sugar, Ten drops, Two times a day for first Three days of period
Category
Placebo

2

Description
Intervention group: Rosaceous Sinensis, Ten drops, Two times a day for first Three days of period
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitory of Hamedan University of Medical Sciences
Full name of responsible person
Dr. Ali Ataei
Street address
Hamedan University of Medical Sciences, next to Luna park, Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Masoumeh Simbar
Street address
School of Nursing and Midwifery, Opp. Shahid Rajaee

Heart Hospital, Niyayesh Crossing, Valie Asr Ave, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

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

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seddighe Amir Ali Akbari

Position

Msc.

Other areas of specialty/work

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Person responsible for updating data

Contact

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