Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Melissa Officinalis extract on the severity of primary dysmenorrhea and related symptoms of Islamic Azad University students in Zanjan

Protocol summary

Summary

This study is a double blind clinical trial. One hundred students with moderate or severe dysmenorrhea will match in terms of dysmenorrhea severity with Visual analogue scale and experience; age; menarche; body mass index (BMI); occupation as well as educational level of parents; and duration, interval as well as amount of bleeding. Then, they will randomly divide into 2 groups, Melissa officinalis (50 subjects) and placebo (50 subjects). In Melissa group, students will give capsules with Melissa (from Zardband Pharmaceuticals, Tehran) 3 times a day over 3 days at the onset of hemorrhage while the Placebo group will give corn starch in similar capsules with the same protocol.The capsules are similar in shape and packaging. Pain severity will evaluate with a visual analogue scale (0 to 10cm) and systemic manifestations with a multidimensional verbal scale before and during 2 consecutive menstrual cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203045975N3**
Registration date: **2012-09-11, 1391/06/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-11, 1391/06/21

Registrant information

Name

Parvaneh Mirabi

Name of organization / entity

Islamic Azad university

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

The Pharmaceutical Sciences Research Center of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-09-05, 1391/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Melissa Officinalis extract on the severity of primary dysmenorrhea and related symptoms of Islamic Azad University students in Zanjan

Public title

The effect of Melissa Officinalis extract on the severity of primary dysmenorrhea and related symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Single;18-26 years old; having moderate and severe dysmenorrhea; not having known chronic disease such as fibromyalgia ; not having vaginal discharge-dysuria- itching; regular menstration; not having history of pelvic inflammatory disease- Fibrom;

Not taking medication; Not having stress condition such as parental separation - death of a family (in 2 month later). Exclusion criteria: Drug intolerance; Lack of proper medication or stop taking the capsules; Taking any herbal medicine in three months prior and during the intervention (except Melissa).

Age
From **18 years** old to **26 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Allocation to group is based on random numbers generated by computer. Both participant and the researcher are blind to the medication becouse of the capsules are similar in shape and packaging.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Science, near the Taleghani hospital,Tabnak St, Evin, Chamran highway, Tehran

City
Tehran

Postal code

Approval date
2011-12-25, 1390/10/04

Ethics committee reference number
89-01-86-7505-6498

Health conditions studied

1

Description of health condition studied
Dysmenorrhea

ICD-10 code
N91.0

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
Dysmenorrhea

Timepoint
one cycle before and two cycles after intervention

Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Severity of bleeding

Timepoint
one cycle before and two cycles after intervention.

Method of measurement
Menstrual pictogram of Campbell and Monga

Intervention groups

1

Description
In Malissa group, students will give capsules of the herb (330 mg) 3 times a day (morning, noon, night), over 3 days at the onset of hemorrhage for two consecutive menstrual cycles.

Category
Treatment - Drugs

2

Description
In placebo group students will give (330 mg) capsules contained starch 3 times a day (morning, noon, night) over 3 days at the onset of hemorrhage for two consecutive menstrual cycles.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dormitory of Islamic Azad university at Zanjan

Full name of responsible person
Parvaneh Mirabi

Street address
Down the mountain lands, Hazrate massomeh

dormitory,Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid beheshti University of Medical Sciences

Full name of responsible person

Dr Mohammad Rahmati Roodsari

Street address

Shahid beheshti University of Medical Sciences, Velenjak,Tehran

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, 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

Zanjan Azad University

Full name of responsible person

Parvaneh Mirabi

Position

Faculty member

Other areas of specialty/work

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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