

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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

+98 24 1422 1001

##### Email address

p\_mirabi@azu.ac.ir

##### 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 because 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

**Street address**  
Islamic Azad University, moalem street, Zanjan

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## Person responsible for scientific inquiries

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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*