

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The Treatment Effect of Peppermint Oil Capsule (Colpermin) for Premenstrual Syndrome

#### Protocol summary

##### Summary

Premenstrual syndrome is a mental, physical and behavioral problem in the reproductive women, and it occurs late of menstrual cycle before or at the onset of menstruation. About 10% of women during the reproductive years are severe premenstrual syndrome that affects the quality of life. Recent favorable treatment is herbal medicine. The purpose of this study is to determine the therapeutic effects of herbal medicine capsules of peppermint oil (Colpermin) on women with premenstrual syndromes. The study protocol is conducted on 60 women (15-20 years old) with a diagnosis of premenstrual syndrome.

Premenstrual symptom is measured using Delany's checklist 28 items during the luteal phase. The minimum and maximum score is between 0 and 84. The women are categorized into two group according the premenstrual syndrome uses cutoff scoring; scores of equal to or less than 15 as no premenstrual syndrome and greater than 15 as premenstrual syndrome. The women with premenstrual syndrome are randomly allocated to oral treatment with Peppermint Oil Capsule (Colpermin) 187 mg or placebo BID for 10 days (from 15 to beginning menstruation) for two cycle (months). After the treatment, the participants will complete the questionnaires again. The women will participate in the study after an informed written consent.

#### General information

##### Acronym

Peppermint Oil Capsule (Colpermin)

##### IRCT registration information

IRCT registration number: **IRCT2016020926446N2**

Registration date: **2016-03-23, 1395/01/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-23, 1395/01/04

##### Registrant information

###### Name

Mouloud Agajani Delavar

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3236 0714

###### Email address

m.aghajani@mubabol.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Babol University of Medical Sciences, Reproductive and Infertility Research Center

##### Expected recruitment start date

2016-03-01, 1394/12/11

##### Expected recruitment end date

2016-10-01, 1395/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Treatment Effect of Peppermint Oil Capsule (Colpermin) for Premenstrual Syndrome

##### Public title

Premenstrual Syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

15-20 years old; mentally healthy; with no history of mental illness; ability to understand the questionnaire; regular menstrual cycles (21-35 days); no history of surgery and death of their relatives within the last 6 months; not taking antidepressants or anti-anxiety during last 3 months; no history of allergy to peppermint and its derivatives; a minimum score of 16 on the basis of Delany's checklist 28 items is to be determined.

#### **Age**

From **15 years** old to **20 years** old

#### **Gender**

Female

#### **Phase**

1-2

#### **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**

### **Secondary IDs**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Babol University of Medical Sciences

###### **Street address**

Ganj Afroz Ave, Babole University of Medical Sciences

###### **City**

Babo

###### **Postal code**

##### **Approval date**

2014-06-01, 1393/03/11

##### **Ethics committee reference number**

2244

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Premenstrual Syndrom

##### **ICD-10 code**

R10.3

##### **ICD-10 code description**

Pain localized to other parts of lower abdomen

### **Primary outcomes**

#### **1**

##### **Description**

mental symptoms

##### **Timepoint**

after 2 month end of consum of drugs

##### **Method of measurement**

Delany's checklist

#### **2**

##### **Description**

behavioral symptoms

##### **Timepoint**

after 2 month end of consum of drugs

##### **Method of measurement**

Delany's checklist

#### **3**

##### **Description**

Physical symptoms

##### **Timepoint**

after 2 month end of consum of drugs

##### **Method of measurement**

Delany's checklist

### **Secondary outcomes**

#### **1**

##### **Description**

Side effects of drugs such as complaints of heart bourn

##### **Timepoint**

end of treatment

##### **Method of measurement**

questionnaire

#### **2**

##### **Description**

Side effects of drugs such as complaints of allergic

##### **Timepoint**

end of treatment

##### **Method of measurement**

questionnaire

#### **3**

##### **Description**

Side effects of drugs such as complaints of hot flash

##### **Timepoint**

end of treatment

##### **Method of measurement**

questionnaire

#### **4**

##### **Description**

Side effects of drugs such as complaints of headaches

##### **Timepoint**

end of treatment  
**Method of measurement**  
questionnaire

## 5

**Description**  
Side effects of mouth ulcer  
**Timepoint**  
end of treatment  
**Method of measurement**  
questionnaire

## **Intervention groups**

### 1

**Description**  
Peppermint Oil Capsule (Colpermin)187 mg BID for 10 days (from15 to beginning menstruation) for two cycle  
**Category**  
Treatment - Drugs

### 2

**Description**  
placebo (the same colpermin), BID for 10 days from15 to beginning menstruation for two cycle  
**Category**  
Placebo

## **Recruitment centers**

### 1

**Recruitment center**  
**Name of recruitment center**  
Babol High School  
**Full name of responsible person**  
Mouloud Agajani Delavar  
**Street address**  
**City**  
Babol

## **Sponsors / Funding sources**

### 1

**Sponsor**  
**Name of organization / entity**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Ali Bijani  
**Street address**  
Gan Afroz Ave, Babol University of Medical Sciences,  
Babol, Iran  
**City**  
Babol  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes  
**Title of funding source**  
Babol 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**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Mouloud Agajani Delavar  
**Position**  
PhD.  
**Other areas of specialty/work**  
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## **Person responsible for scientific inquiries**

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## Person responsible for updating data

### Contact

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**Web page address**

## 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*