Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (from15 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
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Babol University of Medical Sciences
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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 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
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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
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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