

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of combined Lemon balm-Nepeta menthoides and only Lemon balm on students' PMS (Premenstrual Syndrom) and quality of life: a ranomized controlled trial

Protocol summary

Summary

Objectives: This study aims to determine the efficacy of combined Lemon balm-Nepeta menthoides and only Lemon balm on PMS (Premenstrual Syndrom) and quality of life among students. **Design:** a double blind Randomized Controlled Trial. **Setting and conduct:** This study will be conducted in dormitories of Tabriz. Eligible women will be selected with convenience sampling and will be randomly assigned into 3 groups of 93 subjects with block sizes of 3 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelopes will be used for allocation concealment. **Participants:** 93 students with moderate or severe PMS. **Interventions:** First intervention group will receive Lemon balm-Nepeta menthoides Capsule, second intervention group will receive Lemon balm Capsule and third group will receive placebo Capsule. The participant will take drugs one week after the menstruation until the next menstruation bleeding for 14 days, two capsules each day for two consecutive months and they will mark severity of their symptoms in form of DRSP. **Main outcome measures:** Severity of Premenstrual Syndrom and quality of life will be evaluated before intervention and one and two months after the intervention. **Secondary outcomes** include amount of menstruation bleeding, satisfaction from treatment and the frequency of adverse events that will be assessed after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031710324N17**
Registration date: **2014-09-28, 1393/07/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-28, 1393/07/06

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined Lemon balm-Nepeta menthoides and only Lemon balm on students' PMS (Premenstrual

Syndrom) and quality of life: a randomized controlled trial

Public title

The effect of combined Lemon balm-Nepeta menthoides and only Lemon balm on student's PMS (Premenstrual Syndrom) and quality of life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged 18 years and older; Having regular menstrual cycles between 21-35 days; Having a normal BMI (18.5-25) ; Having symptoms in the second half of the cycle; Having symptoms within two cycles before intervention; Having a phone number to follow up; Having tendency to participate in the study
Exclusion criteria: Having depression based on the Beck questionnaire; History of specific diseases (epilepsy, digestive, cardio - vascular, renal, neuro-endocrine) according to the self-reported; Taking an antidepressant, anticonvulsant or herbal, vitamins, hormones drugs in the past 3 months; Drinking alcohol and smoking hookah; Incidence of a stressful incident in the past 6 months; Parental divorce, Death of first degree relatives and etc.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **93**

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 Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, and East

Azerbaijan

City

Tabriz

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

9313

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Intensity of Premenstrual syndrom symptoms

Timepoint

Two cycles Before intervention, 1, 2 cycles during intervention

Method of measurement

DRSP questionnaire

2

Description

Quality of life

Timepoint

Before and at the end of second cycle after intervention

Method of measurement

Quality of life questionnaire-SF-36

Secondary outcomes

1

Description

Amount of menstrual bleeding

Timepoint

Before intervention, first and second cycles during intervention

Method of measurement

Higham chart

2

Description

Satisfaction from treatment

Timepoint

After the end of intervention

Method of measurement

Questionnaire

3

Description

Frequency of adverse events

Timepoint

During intervention

Method of measurement

Checklist

Intervention groups

1

Description

The first intervention groups will receive only Lemon balm 500 mg capsules twice daily.

Category

Treatment - Drugs

2

Description

The second intervention group will receive Lemon balm plus Nepeta menthoides 500 mg capsules twice daily.

Category

Treatment - Drugs

3

Description

The control group will receive 500 mg placebo capsules twice daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

dormitories of Tabriz university of medical sciences

Full name of responsible person

Solmaz Ghanbari

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Rashidi Mohammad Reza

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Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht

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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, Tabriz 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**

Tabriz University of Medical Sciences, Nursing & Midwifery Faculty

Full name of responsible person

Solmaz Ghanbari Homayi

Position

MSc student in Midwifery

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Mojgan Mirghafourvand

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PhD of Reproductive Health

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Web page address

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