

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6969

###### Email address

mirghafourvandm@tbzmed.ac.ir

##### 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

##### **Street address**

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

Street, Azadi Avenue, Tabriz

##### **City**

Tabriz

##### **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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3417174914

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+98 41 1331 2679

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##### **Email**

narvan\_s10@yahoo.com

##### **Web page address**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Tabriz University of Medical Science, Nursing & Midwifery Faculty

##### **Full name of responsible person**

Dr. Mojgan Mirghafourvand

##### **Position**

PhD of Reproductive Health

##### **Other areas of specialty/work**

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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*