Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of combined Lemon balm-Nepeta menthoides and only Lemon balm on students' PMS (Premenstural 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 (Premenstural Syndrom) and quality of life among students. Design: a double blind Randomized Controlled Trial. Setting and conduct: This study will be conducted in dormiotories 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 envelops 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 Premenstural 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

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Tabriz University of Medical Sciences
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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 (Premenstural

Syndrom) and quality of life: a ranomized controlled trial

Public title
The effect of combined Lemon balm-Nepeta menthoides and only Lemon balm on student's PMS (Premenstural 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 Premenstural 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
Statisfaction from tratment
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 intervantion group will recieve Lemon balm plus Nepeta menthoides 500 mg capsules twice daily.
Category
Treatment - Drugs

3

Description
The control group will recieve 500 mg placebo capsules twice daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
dormiotories 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
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Person responsible for scientific inquiries

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Mirghafourvandm@tbzmed.ac.ir;
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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