Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of homeopathy on the pain, menstrual symptoms and quality of life in students with primary dysmenorrhoea: a randomized controlled trial

Protocol summary

Summary

The aim of this trial is to determine effect of homeopathy on menstrual pain severity, menstrual symptoms and quality of life of students with primary dysmenorrhoea. 80 eligible students living in dormitories of Tabriz University of Medical Sciences will be recruited after getting written informed consent. Students will be asked to fill in a form including reports of menstrual pain and symptom severity during four consecutive cycles (two pre- and two post- intervention cycles) and give them to the researcher in every visit. In the second visit, in day of 6-10 of the second menstrual cycle, the researcher will select 60 students from the persons who have filled in the forms carefully and will ask them to complete the SF-36 questionnaire at that time and go to the homoeopath physician in the next 3 days. The physician (with 6 years experience in homeopathy) will visit the participants twice with one month interval and in each visit will give a homeopathic medicine, unique for each participant, to the research assistant. The assistant will give every participant either the prescribed homeopathic remedy (soluble in water) or only water (placebo), according to allocation sequence and will ask them to take it under her supervision. Block randomization with block sizes 4 and 6 using a computerized program will be used to determine allocation sequence. Sequentially numbered opaque sealed envelopes will be used for allocation concealment which will be opened by the resistant at the moment of giving medicine\placebo to each participant. At the end visit (about one month after the second prescription), the participants will fill in the SF-36 questionnaire again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207063706N14**

Registration date: **2012-11-28, 1391/09/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2012-12-05, 1391/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of homeopathy on the pain, menstrual symptoms and quality of life in students with primary dysmenorrhoea: a randomized controlled trial

Public title

Effect of homeopathy on the pain, menstrual symptoms

and quality of life in patients with primary dysmenorrhoea

Purpose
Treatment

Inclusion/Exclusion criteria
Eligibility criteria: age 18-27 years; single; having symptoms of primary dysmenorrhoea; pain severity of moderate to high (4.0-9.1); lack of pelvic and abdomen operations history; lack of allergy; non consumption of contraceptive drugs; non consumption of corticosteroids; non consumption of tobacco products; lack of allergy to Ibuprofen and the availability in visit specified days to visit.

Age
From **18 years** old to **27 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study, the person who will give drug/placebo to the participants can not be blinded. Others (participant, the physician and person who will collect and analyze data) will be blinded. Participants will be instructed not to take drug or other products for pain relief during the 4 months study period. They should take only Gelofen, if necessary, but they have to report the number taken.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences Ethics Committee

Street address
Golgasht

City
Tabriz

Postal code

Approval date
2012-10-29, 1391/08/08

Ethics committee reference number
91131

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhoea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Severity of menstrual pain

Timepoint
During two months pre-intervention and two months after intervention

Method of measurement
Visual analogue scale (VAS)

Secondary outcomes

1

Description
Menstrual symptom severity

Timepoint
During two months pre-intervention and two months after intervention

Method of measurement
Symptom severity scale (SSS)

2

Description
quality of life

Timepoint
at baseline and 2 months after starting intervention

Method of measurement
SF-36

Intervention groups

1

Description
Intervention: Homeopathic medicine, unique for each participant, twice with one month interval prescribed by a Homeopathic physician.

Category
Treatment - Drugs

2

Description
Control: Placebo (water), twice with one month interval,

after visit by a Homeopathic physician

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Dormitory

Full name of responsible person

Street address

City

Tabriz

2

Recruitment center

Name of recruitment center

Fajr Dormtory

Full name of responsible person

Street address

City

Tabriz

3

Recruitment center

Name of recruitment center

Gods Dormitory

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Kazem Shakouri

Street address

Research deputy, Golgasht Ave

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Faculty of Nursing & Midwifery- Tabriz University of Medical Sciences

Full name of responsible person

Khatereh Yousefi Rad

Position

MSc student in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

PhD in reproductive health

Other areas of specialty/work

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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