

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

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

Protocol summary

Registration timing: **registered_while_recruiting**

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.

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)

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+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

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207063706N14**

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

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 Dormitory
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
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Person responsible for scientific inquiries

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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
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Position

PhD in reproductive health

Other areas of specialty/work

Street address

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Postal code

Phone

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Fax

Email

Web page address

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