

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of ethanol extract of Iranian borage (*Echium amoenum*) on pain intensity and quality of life enjoyment and satisfaction of students with primary dysmenorrhea: a randomized controlled trial

Protocol summary

Summary

The aim of this triple-blind randomized controlled trial with two parallel arms is to determine the effect of ethanol extract of Iranian borage (*Echium amoenum*) on pain intensity and quality of life enjoyment and satisfaction (primary outcomes) and menstrual bleeding (secondary outcome). Visual analogue scale, quality of life enjoyment and satisfaction questionnaire and Higham chart will be used to assess the outcomes, respectively. After signing an informed consent, all selected eligible students with moderate to severe primary dysmenorrhea living in Tabriz student dormitories will be asked to take identical analgesic (gelofen capsules) for menstrual pain relief, if needed. They will be asked to record their menstrual pain, number of analgesics used, the quality of life and menstrual blood loss in the following cycle (running period). 70 of them, who had good cooperation, will be allocated into two groups using block randomization with block size of 4 and 6 and allocation ratio of 1:1, stratified by dormitory. Consecutive numbered packs, each containing 18 identical capsules of 500 mg *Echium amoenum* or placebo will be used for the blinding. Each participant will get one of the packs in their recruitment rank, to use the capsules every 12 hours since onset of menstrual pain for 72 hours or until the pain relief, for three following cycles. They will be asked to record the capsule use and any side effects on a diary, in addition to recording menstrual pain, number of the gelofen used, the quality of life and menstrual blood loss, in the three cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601143706N28**

Registration date: **2016-02-29, 1394/12/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-29, 1394/12/10

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

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-07, 1394/12/17

Expected recruitment end date

2016-05-15, 1395/02/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ethanol extract of Iranian borage (*Echium amoenum*) on pain intensity and quality of life enjoyment

and satisfaction of students with primary dysmenorrhea:
a randomized controlled trial

TBZMED.REC.1394.881

Public title

The effect of ethanol extract of Iranian borage on menstrual pain intensity and quality of life enjoyment and satisfaction of students

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) single; 2) age between 18 and 30 years; 3) regular menstrual periods with interval of 21 to 35 days; 4) moderate to severe menstrual pain (above 4.4 mm in 10 cm VAS) over the past 6 months; 5) lack of heavy menstrual bleeding Exclusion criteria: 1) any sensitivity to herbal medicines; 2) smoking or alcohol drinking; 3) any known chronic diseases; 4) no easy access to telephone line for the follow-ups

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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 Deputy, 3rd Floor, Central Building No 2 ,
Tabriz University of Medical Sciences, Golgasht st.,
Tabriz

City

Tabriz

Postal code

Approval date

2016-01-04, 1394/10/14

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

primary dysmenorrhea

Primary outcomes

1

Description

Quality of Life Enjoyment and Satisfaction

Timepoint

1) one cycle before intervention 2) The third cycle after intervention

Method of measurement

Quality of Life Enjoyment and Satisfaction questionnaire

2

Description

Number of Gelofen used

Timepoint

1) one cycle before intervention 2) The first , second and third cycles after intervention

Method of measurement

Visual analogue scale (VAS) for pain

3

Description

Menstrual pain intensity

Timepoint

1) one cycle before intervention 2) The first, second and third cycles after intervention

Method of measurement

Visual Analog scale ((VAS'0-10)

Secondary outcomes

1

Description

Menstrual Symptom Severity

Timepoint

1) one cycle before intervention 2) The first cycle, the second and third after intervention

Method of measurement

Symptom Severity Scale

2

Description

Menstrual blood loss

Timepoint

1) one cycle before intervention 2) The first cycle, second and third cycles after intervention

Method of measurement

Chart Higham

3**Description**

Side effects

Timepoint

The first cycle, the second and third after intervention

Method of measurement

Self report on a diary

4**Description**

Satisfaction with treatment

Timepoint

The first cycle, the second and third after intervention

Method of measurement

self report- one likert question

Intervention groups**1****Description**

Intervention group: taking capsules containing 500 mg Iranian borage (Echium amoenum) every 12 hours, from onset of menstrual pain for 72 hours or until the pain relief for three consecutive cycles

Category

Treatment - Drugs

2**Description**

Control group: taking placebo capsules every 12 hours, from onset of menstrual pain for 72 hours or until the pain relief for three consecutive cycles

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Student dormitories at Tabriz

Full name of responsible person

Farideh quick

Street address

South Shariati, Kosar dormitory

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

Mohammad-Reza Rashidi

Street address

Research Deputy, 3rd floor, Central building No 2, Tabriz University of Medical Sciences, Golgasht st., Tabriz

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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**

Midwifery Department, Nursing & Midwifery Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Farideh Quick

Position

MSc student in Midwifery

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Web page address**Person responsible for scientific inquiries****Contact**

Name of organization / entity

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Full name of responsible person

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Position

PhD in Reproductive Health, Associate Professor

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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