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)

Phone

+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

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, Centeral 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
TBZMED.REC.1394.881

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
Menstural 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
Menstural 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, Centeral building No 2, Tabriz University of Medical Sciences, Golgasht st., 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

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

Full name of responsible person

Farideh Quick

Position

MSc student in Midwifery

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Position
PhD in Reproductive Health, Associate Professor
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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