

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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

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

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

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sakineh Mohammad-Alizadeh-Charandabi

**Position**

PhD in Reproductive Health, Associate Professor

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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**Position**

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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*