

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 2026

### Effects of Capsule *Capsella bursa pastoris* on Primary Dysmenorrhea Severity in Women Referred to Medical Center Affiliated to Kermanshah University of Medical Sciences in 2020

#### Protocol summary

##### Study aim

Assessing the effect of *casella bursa-pastoris* plant on the primary dysmenorrhea severity in women

##### Design

Clinical trials with control group and with parallel groups, triple blind randomized, phase 3 on 80 patients will be done using excel software for randomization.

##### Settings and conduct

Sampling will be done in Imam Reza and Motazeddi hospitals of Kermanshah. The study is triple blind.

##### Participants/Inclusion and exclusion criteria

Participants' pain rated from moderate to severe according to Mac Gill pain scale. They are between 18-30 years old. They have experienced menstrual pain for three consecutive periods in the last 6 months. They have regular menstrual cycles, no chronic disease, no special medication and supplements. Barriers: not willing participants to continue the study. Using other interventions. Allergic reactions in the participants. Using less than 7 capsules in each cycle.

##### Intervention groups

The participants will take 400mg *capsella bursa-pastoris* capsules every 8 hours from the first day of menstrual cycle (second and third) to the third day of menstrual cycle. The participants of the control group will take 250mg Mefenamic Acid capsules following the same prescription of *capsella bursa-pastoris* capsules. If the pain of the individuals in both groups using *capsella bursa-pastoris* and Mefenamic Acid capsules will not decrease using three doses each day every 8 hours the capsules should be used 4 times a day every 6 hours. If they will not recover they can use other painkillers while mentioning its type, doses, and number in questionnaire.

##### Main outcome variables

Severity of primary dysmenorrhea.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200904048614N1**

Registration date: **2020-11-19, 1399/08/29**

Registration timing: **prospective**

Last update: **2020-11-19, 1399/08/29**

Update count: **0**

##### Registration date

2020-11-19, 1399/08/29

##### Registrant information

##### Name

Saeedeh Ahmadipoor

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3826 6937

##### Email address

ahmadipoor.saeideh@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-23, 1399/09/03

##### Expected recruitment end date

2021-05-22, 1400/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effects of Capsule Capsella bursa pastoris on Primary Dysmenorrhea Severity in Women Referred to Medical Center Affiliated to Kermanshah University of Medical Sciences in 2020

## Public title

Effects of Capsule Capsella bursa pastoris on Primary Dysmenorrhea Severity in Women Referred to Medical Center Affiliated to Kermanshah University of Medical Sciences in 2020

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Those with primary dysmenorrhea that their pain rated from moderate to severe according to Mac Gill pain scale. They are between 18-30 years old. They have experienced menstrual pain during the first three days of the menstruation for three consecutive periods in the last 6 months. They have 3-7 days of menstrual bleeding. They do not experience bleeding between two menstrual cycles. They have 21-35-day and regular menstrual cycles. They have no chronic disease (diabetes, hypertension, heart diseases, infectious disease, liver and kidney diseases, epilepsy, and pelvis diseases (fibromas, endometriosis) according to their statements. They have no abnormal vaginal discharge. They do not take special medication and supplements.

### Exclusion criteria:

Those with primary dysmenorrhea that their pain rated as mild according to Mac Gill pain scale. Those with secondary dysmenorrhea. Those with underlying diseases.

## Age

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

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Data analyser

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The simple random sampling and individual entities in random unit will be used. In order to randomize and allocate individuals to groups, random number function will be used. Randomization is as follow using excel software: first, groups will be entered in one column as A,B together; as the number of samples in each group has been defined as 40 (including sample drop), thus, B, A, 40 should be entered in order and beneath. In the other column, using the command RAND, the random numbers are generated. In the next step, using the command sort, the generated random numbers will be organized ranging from lowest numbers to highest ones

or vice versa, this will result a change in groups order as A, B. Using the new order, individuals will be allocated to different groups.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The study is triple blind. This means that the researcher, participants, and statistic consultant will have no information about the drugs used by each group or each A or B packs filled with which type of drugs.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Postal code:6719997788,North Fifth Door,East 3rd Alley,Ostad Shahriyar St.,Justice Town,Kermanshah

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6719997788

#### Approval date

2020-06-15, 1399/03/26

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.091

## 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

Percentage of individual with primary dysmenorrhea whose pain rate is upper than 4 according to Mac Gill pain scale.

#### Timepoint

Measuring the intensity of dysmenorrhea during the first three days of the menstrual cycle ( first month ) without intervention, during the first three days of the menstrual cycle ( second month ) with intervention, during the first three days of the menstrual cycle ( third month ) with intervention.

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: the participants of the intervention group will take 400mg capsella bursa-pastoris capsules three times a day every 8 hours from the first day of menstrual cycle (second and third) to the third day of menstrual cycle (totally 3 days).

**Category**

Treatment - Drugs

**2**

**Description**

Control group:the participants of the control group will take 250mg Mefenamic Acid capsules three times a day every 8 hours from the first day of menstrual cycle (second and third) to the third day of menstrual cycle (totally 3 days).

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Shahram Bidhendi

**Street address**

Imam Reza Hospital,Parastar Boulevard,Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

1533367144

**Phone**

+98 83 3427 6301

**Email**

imamreza@kums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Moatazedi Hospital

**Full name of responsible person**

Mozhgan Rajati

**Street address**

Ferdowsi Square,Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

1447467188

**Phone**

+98 83 3724 6351

**Email**

motazedi@kums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahrokh Dolatian

**Street address**

School of Nursing of Midwifery,In front of Shahid Rajaei Heart Hospital,Niayesh Intersection, Valiasr Street,Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

sbnmf@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Saeedeh Ahmadipoor  
**Position**  
Graduate student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Postal code:6719997788,North Fifth  
Door,Ordibehesht 3rd Alley,Ostad Shahriyar  
St.,Justice Town,Kermanshah  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6719997788  
**Phone**  
+98 83 3826 6937  
**Email**  
saeedahamadipur@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Fateme Nahidi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
School of Nursing and Midwifery,In front of Shahid  
Rajaei Heart Hospital,Niayesh Intersection,Valiasr  
Street,Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 8865 5366  
**Email**  
nahidifateme@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Saeedeh Ahmadipoor  
**Position**  
Graduate student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Postal Code.6719997788,North Fifth  
Door,Ordibehesht 3rd Alley,Ostad Shahriyar St,Justice  
Town  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6719997788  
**Phone**  
+98 83 3826 6937  
**Fax**  
**Email**  
ahmadipoor.saeideh@sbmu.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

-

### When the data will become available and for how long

-

### To whom data/document is available

-

### Under which criteria data/document could be used

-

### From where data/document is obtainable

-

### What processes are involved for a request to access data/document

-

### Comments