Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
saeedehahmadipur@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fatemeh 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