Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

The Effect of Rosa Foetida Extract with Self-care behavior Education on Primary Dysmenorrhea in Female Students of Babol University of Medical Sciences

Protocol summary

Study aim
To determine the effect of Rosa Foetida extract with self-care behavior education on primary dysmenorrhea in female students of Babol University of Medical Sciences

Design
Randomized clinical trial, parallel group trial, single blinded.

Settings and conduct
Study will conduct on volunteer students who have primary dysmenorrhea with severity above 5 based on visual analog scale.The personal information, Menstrual distress questionnaire,self-care behaviors of dysmenorrhea will be obtained.After homogenizing the subjects based on the BMI, menarche age and the mean score of severity of menstrual pain by computerized systemthey will assigned to three groups. All three groups will have two-day training sessions for dysmenorrhea self-care behaviors education.The first group the education will be the only intervention for them.Second group will take Rosa foetida extract(200mg)every 8 hours during first two days of their menstrual cycle for 2 successive cycles as well. TheThird group will take placebo in the same way.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Girls with clinical symptoms of primary dysmenorrhea with a severity score of 5 and more based on the visual analog scale,unmarried , age between 18 and 24 years, BMI between 19 and 30, Regular menses with duration of 35-21 days, menstrual bleeding length of 7 -3 days, willingness to participate in the study
Exclusion criteria: Pain intensity less than 5 based on VAS, history of genico urethral diseases, history of abdomen or pelvis surgery, disorders in renal function,stressful even during last 6 months, lack of cooperation, history of allergy to medicinal plants, use of complementary medicines and Vitamines

Intervention groups
1- Self-care behavior education 2-Self-care behavior education along Rosa foetida extract. 3-Self-care behavior education along Placebo.

Main outcome variables
Dysmenorrhea reduction

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20190318043086N1**
Registration date: **2019-06-14, 1398/03/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-14, 1398/03/24**
Update count: **0**

Registration date
2019-06-14, 1398/03/24

Registrant information

Name
Fatemeh Shabani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3353 8768

Email address
fatemeh.shabani@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Rosa Foetida Extract with Self-care behavior Education on Primary Dysmenorrhea in Female Students of Babol University of Medical Sciences

Public title
The Effect of Rosa Foetida Extract with Self-care behavior Education on Primary Dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Single girls have clinical symptoms of primary dysmenorrhea with pain score (5 or more) based on visual analog scale Clinical symptoms of dysmenorrhea in at least 3 of 6 previous menstrual periods. being single Age of 18 to 24 years Signing Consent Form Body mass index between 19 - 30 Regular cycles with duration of 21- 35 days Length of bleeding 3- 7 days Not having any menstrual cycle disorder during the 3 months before the study Non-steroidal anti-inflammatory and anti-progestin at least a week before start of the period. Non-use of hormonal drugs and oral contraceptives Lack of special diet during the past 3 months The desire to participate in the study

Exclusion criteria:
Pain score less than 5 based on visual analog scale History of genitourinary disease or history of abdominal and pelvic surgery History of blood diseases stomach ache Disorders of the kidney function Stressful accidents over the past six months Discontinue drug use History of allergic diseases History of allergy to medicinal herbs History of allergy with non-steroidal anti-inflammatory drugs Taking supplements and vitamins Unwilling to continue study incomplete questionnaire Probable event of complications History of a prominent physical and psychological problem.

Age
From **18 years** old to **24 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects are assigned to three groups by random blocking and , Students are homogeneous according to body mass index, age of first menstruation and education, and mean score of severity of menstrual pain before treatment and educational actions.

Blinding (investigator's opinion)
Single blinded

Blinding description
Study will be single blind. according to the coding the medicine packs the Participants who receiving will not be aware of the type of the medicine.,

Placebo
Used

Assignment
Parallel

Other design features
does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganj Afroz Street, babol, mazandaran

City
babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Approval date
2019-01-29, 1397/11/09

Ethics committee reference number
IR.MUBABOL.REC.1397.059

Health conditions studied

1

Description of health condition studied
Menstrual pain or Primary Dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
intensity of pain

Timepoint
1،2، 4، 8، 12، 24، 48 The hour after the onset of menstrual pain

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description
Menstrual distress score
Timepoint
One month before the intervention During the first two days of menstruation and in two Consecutive cycles
Method of measurement
Menstrual distress scales

2

Description
Menstrual bleeding severity
Timepoint
One month before the intervention in two Consecutive cycles
Method of measurement
Pictorial Schedule Questionnaire

3

Description
side effects
Timepoint
During two cycles of taking drug
Method of measurement
Ask the participant

4

Description
Number of absent days of class
Timepoint
One month before the intervention and two consecutive cycles
Method of measurement
Ask the participant

Intervention groups

1

Description
Intervention group: Self-care behavior Education.This group will take dysmenorrhea self-care behaviors classes as two-days training sessions, the first and second part of the educational content in one day, and the third and fourth sections on the second day (60 to 90 minutes each day) as lectures and group discussion, practical demonstration. The content of the classes includes: - Anatomy and genital physiology education - Healthy nutrition during menstruation - Isometric exercises - Tips during menstruation - Relaxation techniques (relaxation and musical therapy and breathing) and heat and message therapy. We will ask the students in the group which got dysmenorrhea self care education only as intervention, that define their intensity of menstrual pain by visual analogue scale,1, 2, 4, 8, 12,24 hours after the start of their menstruation in two consecutive menstrual cycles in the first two days of each cycle, and also complete the measure of menstrual distress and the scale of self-care behaviors in dysmenorrhea at the end of the second day.
Category
Lifestyle

2

Description
Control group:Self-care education along placebo. In the training group along placebo in addition to dysmenorrhea self-care education, 200 mg of placebo capsules will be given every 8 hours in the first two days of the cycle for two consecutive cycles, and the intensity of pain will be defined on the visual analog scale.1, 2, 4, 8, 12, 24, 48 hours after the start of treatment. The menstrual distress scale and the dysmenorrhea scale of self-care behaviors in at the end of the second day.
Category
Placebo

3

Description
Intervention group: Dysmenorrhea Self-care education along Rosa foetida extract capsule.Capsules of Rosa foetida extract will be prepared in Pharmacology Laboratory of Babol Medical School.In the training group along Rosa foetida extract in addition to dysmenorrhea self-care education, 200 mg of the extract capsules will be given every 8 hours in the first two days of the cycle for two consecutive cycles, and the intensity of pain will be defined on the visual analog scale.1, 2, 4, 8, 12, 24, 48 hours after the start of treatment. The menstrual distress scale and the dysmenorrhea scale of self-care behaviors in at the end of the second day.Medications will be prepared in the form of placebo capsules and Rosa-foetida extract capsules. They will get coded in the same envelopes, along with the prescription for taking the medicine. Pharmaceutical will be prepared with the help of a medicinal plants specialist in Babol University of Medical Sciences. The medicine will be prepared in the laboratory under relevant rules. To do this, the fruit of Rosa foetida will get dried then by milling to powder and then extracted with 70% ethanol by massaging, then the extract is dispersed using a rotary evaporator under low pressure solvent .The obtained extract will be kept in a freezer in- 21 ° C for the preparation of capsules.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Women dormitory of Babol Medical sciences University

Full name of responsible person
Mohammad Alijani
Street address
Department of Midwifery, Babol University of medical sciences, Ganj afrooz Street, Babol- Iran
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 9592
Fax
+98 11 3219 0181
Email
shomidvar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
Street address
Ganj Afrouz Avenue, Babol University of Medical Sciences, Deputy of Research and Technology, Babol University, Mazandaran Province
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۵۴
Phone
+98 11 3219 7667
Email
rezaghadimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Hajar Pasha
Position
Assistant Professor of Research-Based
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Ganj Afrouz Avenue, Babol University of Medical Sciences, Mazandaran Province
City
babol
Province
Mazandaran
Postal code
47176-47754
Phone
+98 11 3219 7667
Email
dhajarpasha@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Shabnam Omidvar
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Department of Midwifery, Babol University of medical sciences, Ganj afrooz Street, Babol- Iran
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 9592
Email
sh.omidvar@mubabol.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Fateme shabani

Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
1155, in front of the Forensic medicine, Esteghamat St, Shahid Beheshti Highway
City
Rasht
Province
Mazandaran
Postal code
4144956315
Phone
+98 13 3353 8768
Email
fatemeh.shabani@mubabol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
There wont be any information to be shared
When the data will become available and for how long
There wont be any information to be shared
To whom data/document is available
There wont be any information to be shared
Under which criteria data/document could be used
There wont be any information to be shared
From where data/document is obtainable
Dr. Shabnam Omidvar Mobile:09113253139
What processes are involved for a request to access data/document
It will be possible by submitting written request to the Vice Chancellor for Research and Technology of Babol University of Medical Sciences and after getting it confirmed, during a week through researcher.
Comments