Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of traditional medicines of Rheum Palmatum versus Paeonia Officinalis and Mefenamic acid on primary dysmenorrhea : a randomized clinical trial

Protocol summary

Summary

The aim of this study is to compare Iranian herbal medicines of Rheum palmatum versus Paeonia Officinalis and Mefenamic acid on the duration and severity of primary dysmenorrhea as a randomized clinical trial.The study is interventional and double blind.Patients and researcher will be unaware of the contents of the drug package.The sample size is 35 in each group and the study will be done in three groups. Firstly, a brief description of the people who have the criteria for entering the study is taken. After understanding the type of dysmenorrhea, duration and severity, history of previous illnesses and drug use, people who have moderate to severe dysmenorrhea are to be tested. The decision criterion for measuring pain intensity is based on the Visual Analog Scale (VAS) and (VMSS).The population of this study is students living in dormitories of Tabriz University of Medical Sciences. Selection of patients will be available for inclusion in the study. This will continue until the sample size is sufficient.Each patient will be studied in three consecutive cycles. During the first cycle (control cycle), the placebo will be given to patients and patients will be asked to respond to the degree of severity and duration of the pain, along with other symptoms that are in the questionnaires and forms. During the second and third cycles of the capsule containing the Rivand root into the test group one, the capsule containing peony was given to the experimental group 2 and capsule containing MEFNAMIC ACID to the third group.The necessary information on the way the drug is used by the researcher is provided orally and in writing to the patient. The dosage is given from the day before the menstruation up to 5 days later, as an 8-hour period and followed up for three consecutive cycles.If the symptoms of a patient's pain are resolved sooner, the drug will continue until one day after the symptoms are resolved. If within 3 months, the patient has not stayed in the study or within 3 months of one of the conditions, including underlying illness, heart disease or any metabolic problem was fixed, or the patient used another medicine to relieve pain, will be excluded. Inclusion criteria: 18_35years old Regular menstruation Severity of pain moderate to severe Exclusion criteria: Pregnancy Uterine infections Irregular mense

General information

Acronym

Interventional

IRCT registration information

IRCT registration number: **IRCT2017062834784N1**
Registration date: **2017-07-07, 1396/04/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-07, 1396/04/16

Registrant information

Name

Farrin Rajabzadeh

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 9528

Email address

rajabzadehf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date
2017-07-23, 1396/05/01
Expected recruitment end date
2017-12-22, 1396/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of traditional medicines of Rheum Palmatum versus Paeonia Officinalis and Mefenamic acid on primary dysmenorrhea : a randomized clinical trial

Public title
Effect of traditional medicines of Rheum Palmatum versus Paeonia Officinalis on primary dysmenorrhea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 18_35years old;Regular menstruation;Severity of pain moderate to severe
Exclusion criteria: Pregnancy;Uterine infections;Irregular mense;Allergy to drug;Chronic disease;Acute systemic disease;Pelvic inflammation disease;Tumor and fibrom;Pelvic and abdoman surgery;Stress trigger ;Constipation and hemorrhoid;Psychological disease
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
In this study, randomization will be randomly done with fixed size blocks (Fixed size block randomization) and will be performed in six blocks.The random numbers will be used to select blocks.

Secondary Ids

1

Registry name
IRTC
Secondary trial Id
Prospective registration
Registration date
2017-05-01, 1396/02/11

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz
Postal code
Approval date
2017-06-21, 1396/03/31
Ethics committee reference number
IR.TBZMED.REC.1396.244

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea
ICD-10 code
N94.4
ICD-10 code description
Menstruation painful

Primary outcomes

1

Description
Duration of mense
Timepoint
Monthly
Method of measurement
Hours

2

Description
Severity of pain
Timepoint
Monthly
Method of measurement
VAS and VMSS

3

Description
Quality of life
Timepoint
Monthly
Method of measurement
questionnaire

4

Description
Volume of menstruation
Timepoint
Monthly
Method of measurement
Higham chart

Secondary outcomes

1

Description
To determine the potential adverse events resulting from treatment process in patients in the intervention groups
Timepoint
During the study
Method of measurement
questionnaire-Observation-reportage

Intervention groups

1

Description
A capsule of 500 mg of whole root powder of Rheum palmatum is taken from the day before the menstruation up to five days later every 8 hours and, if the symptoms resolve,you could cut it off.
Category
Treatment - Drugs

2

Description
A capsule of 500 mg of whole root powder of paeonia officinalis is taken from the day before the menstruation up to five days later every 8 hours and, if the symptoms resolve,you could cut it off.
Category
Treatment - Drugs

3

Description
A capsule of 500 mg of powder of starch is taken from the day before the menstruation up to five days later every 8 hours for the first cycle.
Category
Placebo

4

Description
A capsule of 250 mg of mefenamic acid is taken from the day before the menstruation up to five days later every 8 hours and, if the symptoms resolve,you could cut it off.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Dormitory of tabriz university of medical sciences
Full name of responsible person
Street address
South shariati avenue,next to nursing faculty
City
Tabriz

2

Recruitment center
Name of recruitment center
Fajr Dormitory of tabriz university of medical sciences
Full name of responsible person
Street address
Rah ahan street,next to babak hospital.
City
Tabriz

3

Recruitment center
Name of recruitment center
Bahar Dormitory of tabriz university of medical sciences
Full name of responsible person
Street address
Nesf rah avenue,kooche bagh street.
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
Dr.Mohammad Reza Rashidi
Street address
No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, 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
School of Traditional Medicine, Tabriz University of Medical Sciences
Full name of responsible person
Dr mohammad bagher fazljou
Position
Director of the traditional medicine department
Other areas of specialty/work
Street address
School of Traditional Medicine, Central Library of Tabriz University of Medical Sciences, Tabriz University, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 3337 9529
Fax
Email
dr.fazljou@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Traditional Medicine, Tabriz University of Medical Sciences
Full name of responsible person
Farrin rajabzadeh
Position
PHD student of traditional medicine
Other areas of specialty/work
Street address
School of Traditional Medicine, Central Library of Tabriz University of Medical Sciences, Tabriz University, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 3337 9529
Fax
Email
Far.rajabzadeh1@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
School of Traditional Medicine, Tabriz University of Medical Sciences
Full name of responsible person
Farrin rajabzade
Position
PHD student of traditional medicine
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
Far.rajabzadeh1@Gmail.com
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