Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the efficacy of Rosa damascena extract and mefenamic acid on the severity of the primary dysmenorrhea pain: A double – blind randomized controlled trial

Protocol summary

Summary

Objective: Comparison of the efficacy of Rosa damascena extract and mefenamic acid on the severity of the primary dysmenorrhea pain. This study is designed as a randomized clinical, double-blind, single center and phase 3 trial. Students of Tabriz University of Medical Science residing in kowsar dormitory fulfilling inclusion and exclusion criteria such as suffering from primary dysmenorrhea pain of 5-8 in vas system, absence of previous underlying genital disease, absence of previous abdomino-pelvic surgery will be enrolled in the study after signing the informed consent sheet. 92 students (sample size) will be randomly allocated to two groups and will be treated for 3 consecutive days with either mefenamic acid or Rosa damascena extract for a single cycle; then for the next cycle the group using mefenamic acid will receive Rosa damascena extract and vice versa. primary outcome is defined as the severity of dysmenorrhea pain and is measured using VAS system before and after interventions in predefined intervals . Primary outcome will be compared between two groups to assess the analgesic efficacy of mefenamic acid and Rosa damascena extract.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207267618N2**
Registration date: **2012-09-16, 1391/06/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

Name

Soheila Bani

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Sience

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Rosa damascena extract and mefenamic acid on the severity of the primary dysmenorrhea pain: A double – blind randomized controlled trial

Public title

Comparison of the efficacy of Rosa damascena extract and mefenamic acid on the severity of the primary dysmenorrhea pain

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: women with abdominal pain compatible with dysmenorrhea; being single; signing the informed consent sheet. Exclusion criteria: pain severity more than 8 or less than 5 according to visual analogue scale system; history of genitourinary disease or abdomino-pelvic surgery; stressful event(loss); lack of compliancy; history of hypersensitivity to mefenamic acid; using drugs that interact with mefenamic acid.
Age
From **18 years** old to **30 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research deputy of Tabriz University of Medical Sience
Street address
Central department of Tabriz University of Medical Sience, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
51665118
Approval date
2012-05-28, 1391/03/08
Ethics committee reference number
9159

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
severity of dysmenorrhea pain
Timepoint
before the first intervention, after the first intervention, before the second intervention, after the second intervention
Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:oral capsules containing 200 mg of Rosa damascena extract every 6 hours for the first 3 days of menstruation.
Category
Treatment - Drugs

2

Description
Control group: Oral capsules containing 250 mg of mefenamic acid every 6 hours for the first 3 days of menstruation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar dormitory of Tabriz University of Medical Sience
Full name of responsible person
Zeinab alsadat Moosavi
Street address
Kowsar dormitory of Tabriz University of Medical Sience, South Shariaty street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tabriz University of Medical Sience
Full name of responsible person
Dr Mohammadreza rashidi
Street address
Golgasht street, Azadi 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
Research deputy of Tabriz University of Medical Sience
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

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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