

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

banis@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Research deputy of Tabriz University of Medical Science

#### 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 Science

##### Street address

Central department of Tabriz University of Medical Science, 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 Science

##### Full name of responsible person

Zeinab alsadat Moosavi

##### Street address

Kowsar dormitory of Tabriz University of Medical Science, South Shariaty street, Tabriz

##### City

Tabriz

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Research deputy of Tabriz University of Medical Science

**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 Science

**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**

Tabriz University of Medical Science

**Full name of responsible person**

Zeinab alsadat Moosavi

**Position**

MSC student of midwifery

**Other areas of specialty/work****Street address**

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zeimous\_hk@yahoo.com

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Faculty of nursing and midwifery, Tabriz University of Medical Science

**Full name of responsible person**

Soheila Bani

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### Person responsible for updating data

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Faculty of nursing and midwifery, South Shariaty street, Tabriz

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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*