

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of willow bark on primary dysmenorrhea in female students

#### Protocol summary

##### Study aim

compare the Effect of Mefenamic Acid and willow bark in the of Dysmenorrhea among students.

##### Design

The study was Randomization, double-blind, active control, cross-over trial. Study was 2-sequence crossover design over consecutive menstrual cycles (two treatment periods) .

##### Settings and conduct

This study was a double-blind cross-over randomized clinical trial that was performed on 275 Students In the nearest dormitory of the Shahrekord University of Medical Sciences over 6 months .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :being single, suffering from level two or three primary dysmenorrhea , absence of any genital organs diseases , having no systemic diseases ,surgery during the past 8 weeks; ,hormonal therapy during the last 6 months and hypersensitivity to aspirin , having regular menstrual cycles, using no contraceptives.

Exclusion criteria: non-responsive menstrual pain to NSAID in the past, history of hypersensitivity to NSAIDs

##### Intervention groups

During the first two cycles, the severity of dysmenorrhea was measured Students were randomly allocated into either treatment using randomized block design in the two next consecutive cycles. In cycle 3, group A received willow bark capsule as the intervention and group B received mefenamic acid capsule as the active control. In cycle 4, patients in group A received mefenamic acid capsule and group B patients received willow bark capsule

##### Main outcome variables

The pain level experienced by the students was assessed by visual analog scale . The secondary outcome measures are the menstrual symptom scale. Pictorial blood assessment chart, The bleeding amount was measured using chart

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180123038486N1**

Registration date: **2018-11-01, 1397/08/10**

Registration timing: **retrospective**

Last update: **2018-11-01, 1397/08/10**

Update count: **0**

##### Registration date

2018-11-01, 1397/08/10

##### Registrant information

##### Name

Ziba Raisi Dehkordi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3224 0556

##### Email address

ziba758@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2015-01-10, 1393/10/20

##### Expected recruitment end date

2016-01-30, 1394/11/10

##### Actual recruitment start date

2015-05-10, 1394/02/20

##### Actual recruitment end date

2016-02-09, 1394/11/20

##### Trial completion date

2017-12-10, 1396/09/19

##### Scientific title

Effect of willow bark on primary dysmenorrhea in female

students

**Public title**

willow bark and dysmenorrhea

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

suffering from level two or three primary dysmenorrhea according to the Andersch and Milsom's verbal multi-dimensional scoring system aged 18 to 28 years old regular menstrual cycles without history of allergy to willow bark single students

**Exclusion criteria:**

absence of any genital organs diseases history of hypersensitivity to NSAIDs systemic diseases neurologic or psychiatric disease surgery during the past eight weeks hormonal therapy during the last six months used contraceptives

**Age**

From **18 years** old to **28 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **110**

Actual sample size reached: **98**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Students were randomly allocated into either treatment using randomized block design in the two next consecutive cycles

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The capsules of Willow bark extract were produced with the same appearance, color and odor as Mefenamic acid capsules.

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

No

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

The Ethics Committee of Shahrekord University of Medical Sciences

**Street address**

Deputy for Research, second Floor, the central structure of shahrekord University of Medical Sciences

**City**

shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8817846935

**Approval date**

2013-01-08, 1391/10/19

**Ethics committee reference number**

91-10-23

**Health conditions studied**

**1**

**Description of health condition studied**

primary dysmenorrhea

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

pain level

**Timepoint**

Before intervention and After Intervention

**Method of measurement**

visual analog scale (VAS).

**2**

**Description**

menstrual symptoms

**Timepoint**

Before intervention and After Intervention

**Method of measurement**

COX menstrual symptom scale

**3**

**Description**

bleeding amount

**Timepoint**

Before intervention and After Intervention

**Method of measurement**

Pictorial blood assessment chart

**Secondary outcomes**

**1**

**Description**

Safety and adverse event

**Timepoint**

After intervention  
**Method of measurement**  
case-report form.

## Intervention groups

### 1

#### Description

Intervention group:received willow bark extract capsule (240 mg salicin ) with Placebo three times daily, produced by Medical Plants Research Center, Basic Health Sciences Institute, Shahrekord University of Medical Sciences, Shahrekord, Iran. The treatments were administered to the students for 1 h after experiencing dysmenorrhea until pain relief, for 4 cycles.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: control group: received Mefenamic acid capsule 250mg, three times daily,produced by Razak pharmaceutical company of Iran , 1 h after experiencing dysmenorrhea until pain relief, for 4 cycles.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

dormitory of the Shahrekord University of Medical Sciences

##### Full name of responsible person

Ziba Raisi Dehkordi

##### Street address

Rahmateye.dormitory of the Shahrekord University of Medical Sciences

##### City

Shahrekord

##### Province

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##### Postal code

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##### Phone

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##### Email

ziba758@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Ziba Raisi Dehkordi

#### Street address

Number 4, Melat Avenue, Shahrekord University of Medical Sciences

#### City

Sharekord

#### Province

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#### Phone

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#### Email

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#### Grant name

12

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Ziba Raisi Dehkordi

##### Position

Master of Science in Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Master of Midwifery

**Latest degree**

Master

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## Person responsible for updating data

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Shahre-kord University of Medical Sciences

**Full name of responsible person**

Ziba Raisi Dehkordi

**Position**

Master of nursing

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Email**

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## 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**

No more information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable