Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Randominization, 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Number 4, Melat Avenue, Shahrekord Univercity of Medical Sciences

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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

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Position
Master of Midwifery

Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Master

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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