Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The comparison of Shirazi Thymus Vulgaris and Ibuprofen effects on the severity of primary dysmenorrhea n female student campuses Ilam University of Medical scinces in 2009

Protocol summary

Summary

Background: Primary dysmenorrhea defined as painful cramps during menstruation with no pelvic pathology. The Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are considered the most common pharmacologic treatment. The present study was conducted to compare the effects of Shirazi Thymus Vulgaris and Ibuprofen on primary dysmenorrhea due to adverse effects of NSAIDs. Methods and Materials: A randomized, single-blind clinical trial was conducted amongst 120 female students at the Ilam University of Medical Sciences campuses, aged 18 to 25 years who suffered from primary dysmenorrhea. Inclusion criteria including: suffered from primary dysmenorrhea ;single;Ilam University of Medical Sciences campuses and excluding criteria including: Diabetes mellitus;taking certain medications;stressors in the past three months;irregular menstruation ;abnormal discharge The participants were randomly divided into two groups of herbal and classic treatments. The first herbal group received the Shirazi Thymus Vulgaris commercially named BronchoT.D 5cc orally QID. The second classic group received Ibuprofen; three tablets orally daily. A visual analogue scale (VAS) was used to record pain severity.Systemic symptoms were compared using multi-dimensional measure during two consecutive menstrual cycles.Data were analyzed using descriptive statistics, inferential, statistical inference, indicators mean and SD and Whitney test, Friedman and Wilcoxon

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105236575N1**
Registration date: **2011-06-13, 1390/03/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-13, 1390/03/23

Registrant information

Name

Ashraf Direkvand-Moghadam

Name of organization / entity

Ilam University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ilam University of Medical Sciences

Expected recruitment start date

2009-11-22, 1388/09/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Shirazi Thymus Vulgaris and Ibuprofen effects on the severity of primary dysmenorrhea n female student campuses Ilam University of Medical scinces in 2009

Public title
The comparison of Shirazi Thymus Vulgaris and Ibuprofen effects on the severity of primary dysmenorrhea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: suffered from primary dysmenorrhea ; single;Ilam University of Medical Sciences campuses; Excluding criteria: Diabetes mellitus;taking certain medications;stressors in the past three months;irregular menstruation ;abnormal discharge
Age
From **18 years** old to **25 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
the Ilam University of Medical Sciences
Street address
the Ilam University of Medical Sciences
City
Ilam
Postal code
Approval date
2008-10-11, 1387/07/20
Ethics committee reference number
5195/40/22

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea
ICD-10 code
N94.4
ICD-10 code description
Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
Dysmenorrhea severity
Timepoint
Two months before the intervention and intervention for two consecutive menstrual cycles
Method of measurement
VAS method

Secondary outcomes

1

Description
duration of pain
Timepoint
Two months before the intervention and intervention for two consecutive menstrual cycles
Method of measurement
Cox Menstrual Symptom Scale

Intervention groups

1

Description
classic group received Ibuprofen; three tablets orally daily from the first day until had pain score more than 3 during menstruation
Category
Treatment - Drugs

2

Description
The herbal group received the Shirazi Thymus Vulgaris commercially named BronchoT.D 5cc orally QID from the first day until had pain score more than 3 during menstruation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar, Ilam University of Medical Sciences campuse
Full name of responsible person
BA of Midwifery
Street address

Kosar campuses.Ilam University of Medical Sciences

City

Ilam

2

Recruitment center

Name of recruitment center

Hejab campuse.Ilam University of Medical Sciences

Full name of responsible person

BA of Midwifery

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Hejab campuse.Ilam University of Medical Sciences

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ilam University of Medical Sciences

Full name of responsible person

Dr Afra Khosravi research manager of research, Ilam University of Medical Sciences

Street address

Vice chancellor for research Ilam University of Medical Sciences, Pajuhesh Avenue, Bangnjab, Ilam

City

Ilam

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, Ilam 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

Department of Midwifery,Faculty of Nursing and Midwifery,Ilam University of Medical Sciences

Full name of responsible person

Ashraf Direkvand-Moghadam (MSc)

Position

MSc

Other areas of specialty/work

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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