

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

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

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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 sciences 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

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2

Recruitment center

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