

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The comparison of Shirazi thymus vulgaris and Ibuprofen effects on primary dysmenorrhea (A double blind clinical trial)

Protocol summary

Summary

The aim of this randomized, double blind trial is to investigate an alternate herbal treatment for dysmenorrhea. In this study, 84 patients with dysmenorrhea who meet the inclusion/exclusion criteria will be recruited and randomly assigned into the three following groups. The patients in the intervention group will receive origanum vulgare or Ibuprofen as well as placebo and the patients in the control group will receive placebo with similar form and dose. Intensity of dysmenorrhea will be measured by using visual analog scale (VAS) and compared between groups.

General information

Acronym

CSTVIPD

IRCT registration information

IRCT registration number: **IRCT201101245683N1**

Registration date: **2011-06-03, 1390/03/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-03, 1390/03/13

Registrant information

Name

Hajar salmalian

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences, Barij Essence corporation, Kashan

Expected recruitment start date

2011-04-03, 1390/01/14

Expected recruitment end date

2011-10-06, 1390/07/14

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 primary dysmenorrhea (A double blind clinical trial)

Public title

An alternate herbal treatment for dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: single 18 to 24 years old midwifery and nursing students with no history of abdominal or pelvic surgery or any specific disease who were suffering from primary dysmenorrhea grade 1 or 2 Exclusion criteria: improper administration of the medication, administration of contraceptive pills or another medication whilst on research, history of allergies to origanum vulgare, severe stress, heavy exercise

Age

From **18 years** old to **24 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Other

Other design features

All individuals have the right to use their own medication of choice in case of no response to the intended treatment, though they are obliged to report the time and reason of administering the new medication as well as their pain score prior to taking the drug. Such individuals would not be eliminated from the study, they would be considered as failure to treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences

City

Babol

Postal code

4774547176

Approval date

2011-02-22, 1389/12/03

Ethics committee reference number

3150

Health conditions studied

1

Description of health condition studied

Dysmenorrhea

ICD-10 code

O94-O99

ICD-10 code description

Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description

Primary dysmenorrhea

Timepoint

Prior to the intervention, 2 months after the initiation of intervention (2 first days of 2 subsequent cycles)

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

cap Ibuprofen 200 mg + 25 drop placebo (Orally administrated every 6 hours (PO,QID) in the first 2 days of 2 subsequent cycles.)

Category

Treatment - Drugs

2

Description

25 drops thymus vulgaris+ cap placebo 200 mg (Orally administrated every 6 hours (PO,QID) in the first 2 days of 2 subsequent cycles)

Category

Treatment - Drugs

3

Description

25 drops placebo + cap placebo 200 mg (Orally administrated every 6 hours (PO,QID) in the first 2 days of 2 subsequent cycles.)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol University of Medical Sciences

Full name of responsible person

Hajar Salmalian- Midwifery MSc(Faculty Member)

Street address

Babol University of Medical Sciences

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Amrollah Mostafazadeh

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Grant name**Grant code / Reference number**

8929912

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

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Roshanak Saghebi

Position

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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*