Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

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

Protocol summary

Summary
The aim of this randomized, double blind trial is to investigate an alternate herbal treatment for dysmenorrehea. In this study, 84 patients with dysmenorrehea 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

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Iran (Islamic Republic of)

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+98 112199595

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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 dysmenorrheal (A double blind clinical trial)

Public title
An alternate herbal treatment for dysmenorrehea

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 dysmenorrehea 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 administrating 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
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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
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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

Street address
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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
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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