

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparing the analgesic effect of extra virgin olive oil and ibuprofen for primary dysmenorrhea in students residing in dormitories of Borujerd islamic azad university: A randomized, Cross-Over clinical trial

Protocol summary

2013-07-23, 1392/05/01

Summary

Objective: The aim of this study was to compare the analgesic effect of extra virgin olive oil with ibuprofen on pain relief in primary dysmenorrhea. Design: The present study was a cross-over, randomized clinical trial. Setting and conduct: The study was conducted at Borujerd islamic azad University Dormitory. Participants including major eligibility criteria: Sixty 17 to 30 years old students with moderate to severe primary dysmenorrhea using MC Gill pain scale were selected to participate in this study. Based on random numbers table, the samples were equally divided into two groups. Intervention: The participants in the first group took 25 cc of extra virgin olive oil daily, (two weeks before menstruation until two months after menstrual cycle for two consecutive cycles). After 3 weeks washed out period, they use ibuprofen 400 mg three times a day in the 3 first days of menstruation. alternative was used for the second group. A self-reported checklist was used to collect information on the number of sedative drugs and condition of menstrual. Also visual analog scale was used to determine severity of pain. Main outcome variable: Severity of primary dysmenorrhea and the other menstruation problems were assessed after 4 menstruation periods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051110804N2**

Registration date: **2013-07-23, 1392/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Marzieh Araban

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

تهران

Email address

m.araban@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Islamic azad university, Borujerd branch

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2011-03-03, 1389/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the analgesic effect of extra virgin olive oil and ibuprofen for primary dysmenorrhea in students residing in dormitories of Borujerd islamic azad university: A randomized, Cross-Over clinical trial

Public title

Comparing the analgesic effect of extra virgin olive oil and ibuprofen for primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Not being married, 17 to 30 years old; living in Islamic Azad university Borujerd branch dormitory; having score 4 to 10 for dysmenorrhea according to pain scale; having regular menstrual periods between 21 to 35 days, no history of myoma, pelvic tumor, endometriosis and pelvic inflammatory disease; no taking oral particular drug, no history of allergy to herbal drugs. Exclusion criteria: allergy to olive oil or non-steroidal anti inflammatory drugs;taking inappropriate dosage and forgetting the time table.

Age

From **17 years** old to **30 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic azad university, Borujerd branch

Street address

Pardis Imam Khomeini, Yadegare Imam, Nvab Square, Borujerd

City

Borujerd

Postal code

Approval date

2009-09-23, 1388/07/01

Ethics committee reference number

1112/13

Health conditions studied

1

Description of health condition studied

dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

dysmenorrhea

Primary outcomes

1

Description

Severity of primary dysmenorrhea

Timepoint

4 menstrual cycles, one cycle before the study and 2 cycles during the study after using extra virgine oil and 2 cycles after taking ibuprofen

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

Nausea

Timepoint

Before and after the treatment

Method of measurement

Questionnaire

2

Description

Diarrhea

Timepoint

Before and after the treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

First treatment/ control group:taking daily 25 cc of extra virgin olive oil for 2 months, Then ibuprofen 400 mg, three times a day for 2 cycles during the 3 first days of menstruation.

Category

Treatment - Drugs

2

Description

The second treatment/ control group: taking ibuprofen 400 mg three times a day during first 3 days of menstruation, Then, taking daily 25 cc of extra virgin olive oil, for 2 menstrual cycles.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Borujerd Islamic Azad University dormitory

Full name of responsible person

Maryam Rezaeyan

Street address

Pardis Imam Khomeini, Yadegare Imam, Nvab Square, Borujerd

City

Borujerd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic azad university, Borujerd branch

Full name of responsible person

Mohammad Jafar Mahdian

Street address

Imam Khomeini paradis university, Yadegare Imam street, Navab Sq

City

Borujerd

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, Islamic azad university, Borujerd branch

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

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad university, Borujerd branch

Full name of responsible person

Maryam Rezaeyan

Position

MSc in midwifery

Other areas of specialty/work**Street address**

Pardis Imam Khomeini, Yadegare Imam, Nvab Square, Borujerd

City

Borujerd

Postal code**Phone**

+98 66 2445 3000

Fax**Email**

rezamaryam@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz Jondishapur University of Medical Sciences

Full name of responsible person

Marzieh Araban

Position

Ph.D

Other areas of specialty/work**Street address**

Pardis Ahvaz Jondishapur University of Medical Sciences, Golestan street, Golestan Square, Ahvaz

City

Ahvaz

Postal code

6163763463

Phone

+98 61 1373 8269

Fax**Email**

arabanm@ajums.ac.ir

Web page address

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