Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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

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 t0 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 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 mensturation 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

2013-07-23, 1392/05/01

Registrant information

Name
Marzieh Araban
Name of organization / entity
Tarbiat Modares University
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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 committe 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 د

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

Treatment - Drugs

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

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Pardis Imam Khomeini, Yadegare Imam, Nvab Square, Borujerd

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Person responsible for updating data

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Position
Ph.D

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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