

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The comparison Of the effect of Heat Patch and Ibuprofen On Intensity primary Dysmenorrhea In The Students' Zahedan University Of Medical Science

Protocol summary

Summary

Abstract Objective: This study was designed to compare the analgesic effect of Heat Patch containing Iron Chip with ibuprofen for primary dysmenorrhea. **Inclusion Criteria:** pain or cramp during menstruation; unable to relieve pain and suffering. **Exclusion criteria:** The history of severe menstrual bleeding; body mass index(BMI)> 30; medical and mental illness ; and smoking (cigarettes, ...) ; use of oral contraceptive; unpleasant event or death of near family ; and continuous exercise(during the past six months); scratch the skin in the lower abdomen;vaginal infection **Population:** university student **Sample size:**147 **Intervention:** The participants were randomly assigned into one of the intervention groups (Heat Patch and Ibuprofen), heat patch attached lower abdomen skin in group 1, and ibuprofen used in group2 , if dysmenorrhea untreated, use of ibuprofen after 8 hours . **Time intervention:** initial menstruation Heat Patch during 8 hr and Ibuprofen q8hr **Primary outcome measure:** intensity primary dysmenorrhea on 2,4,8,12,and 24 hr after initial menstruation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107187038N2**
Registration date: **2011-08-15, 1390/05/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-15, 1390/05/24

Registrant information

Name

Shahin Dokht Navvabi-Rigi

Name of organization / entity

Zahedan University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 54 1242 1259

Email address

navabi_rigi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy Research Of Zahedan University Of Medical Science

Expected recruitment start date

2007-11-01, 1386/08/10

Expected recruitment end date

2008-12-30, 1387/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison Of the effect of Heat Patch and Ibuprofen On Intensity primary Dysmenorrhea In The Students' Zahedan University Of Medical Science

Public title

Effect of heat patch on dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: pain or cramp during menstruation; unable to relieve pain and suffering. **Exclusion criteria:** The history of severe menstrual bleeding; body mass

index(BMI)> 30; medical and mental illness ; and smoking (cigarettes, ...) ; use of oral contraceptive; unpleasant event or death of near family ; and continuous exercise(during the past six months); scratch the skin in the lower abdomen;vaginal infection

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **147**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University Of Medical Science

Street address

Deputy Research; Pardis Of Zahedan university Of Medical Science; Meidan Dr Hesabi; Zahedan; Sistan & Bluchestan; Iran

City

Zahedan

Postal code

Approval date

2011-07-31, 1390/05/09

Ethics committee reference number

90002

Health conditions studied

1

Description of health condition studied

primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

primary dysmenorrhea

Primary outcomes

1

Description

Intensity Primary Dysmenorrhea

Timepoint

initial 2-4-8-12-24hr

Method of measurement

MCGILL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Heat pach group:one pach during initial pain apply on lower abdomen to 8 h,after the demand use of ibuprofen

Category

Prevention

2

Description

control group:400 mg ibuprofen q 8 h

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitory student(deputy of research)

Full name of responsible person

Sodabeh Hashemzahi

Street address

Zahedan University of medical science

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy Research Of Zahedan University Of Medical Science

Full name of responsible person

Sodabeh Hashemzahi

Street address

Pardis -Zahedan University Of Medical Science; Meidan Dr Hesabi; Zahedan; Sistan & Bluchestan; Iran

City

Zahedan

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Deputy Research Of Zahedan University Of Medical Science
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
 Zahedan University of medical science
Full name of responsible person
 Shahin-Dokht Navvabi-Rigi
Position
 mastery of midwifery
Other areas of specialty/work
Street address
 Post box1379; Nursing and Midwifery School; Meidan Mashahir; Zahedan; Sistan and Bluchestan; Iran
City
 Zahedan
Postal code
Phone
 +98 915 997 6642
Fax
Email
 navabi_rigi@zaums.ac.ir shahinnavabi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Zahedan University Of Medical Science
Full name of responsible person
 Shahin-Dokht Navvabi-Rigi
Position

Tutor
Other areas of specialty/work
Street address
 Post box1379; Nursing and Midwifery School; Meidan Mashahir; Zahedan; Sistan and Bluchestan; Iran
City
 Zahedan
Postal code
Phone
 +98 54 1242 1259
Fax
Email
 navabi_rigi@zaums.ac.ir shahinnavabi@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Zahedan University Of Medical Science
Full name of responsible person
 Shahin-Dokht Navvabi-Rigi
Position
 tutor
Other areas of specialty/work
Street address
 Post box1379; Nursing and Midwifery School; Meidan Mashahir; Zahedan; Sistan and Bluchestan; Iran
City
 Zahedan
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Phone
Fax
Email
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