Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of ice massage on the Huko point (LI4) and SP6 on the severity of primary dysmenorrhea of students in two intervention groups and one control group

Protocol summary

Study aim
The aim of this study was to compare the effect of ice massage on the Huko point and SP6 on the severity of primary dysmenorrhea of female students.

Design
A single-blind clinical trial with a control group

Settings and conduct
This study was performed in dormitories in Zabol University of Medical Sciences. To this end, 90 students were selected and divided into three groups of 30 students each.

Participants/Inclusion and exclusion criteria
The inclusion criteria were painful menstrual periods in most menstrual cycles over the past year, Pain score of more than 4 based on visual pain assessment scale, aged 18 to 28 years, having regular menstruation (Duration of 3 to 7 days and two-twelve days from 21 to 35 days), No history of uterine and pelvic disorders, no pregnancy, no use of oral contraceptive pills and no history of abdominal or pelvic surgery. Exclusion criteria were smoking in the last six months, exercise professionally in the last six months, the presence of severe stressors in the last six months, Deaths of first-class family members, parental divorce, non-occurrence of menstruation, consumption of more than two dwellings during the study, using hot and cold therapy, taking herbal drugs to reduce menstrual pain and using massage techniques except of the accepted technique of study.

Intervention groups
first group: Ice massage was performed on Huko spot in a rotary manner daily for 20 minutes until the onset of primary dysmenorrhea. Second group: Ice massage was performed on spatial 6 in a rotary manner daily for 20 minutes and until the onset of primary dysmenorrhea. control group: In the control group, ice massage was performed on an inapplicable spot (except Huko and SP6) daily for 20 minutes and until the onset of primary dysmenorrhea.

Main outcome variables
Primary dysmenorrhoea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180329039156N1**
Registration date: **2018-05-01, 1397/02/11**
Registration timing: **retrospective**

Last update: **2018-05-01, 1397/02/11**
Update count: **0**

Registration date
2018-05-01, 1397/02/11

Registrant information

Name
Hosien Shahdadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3222 5402

Email address
shahdadi@zbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-21, 1396/12/02

Expected recruitment end date
2018-03-22, 1397/01/02

Actual recruitment start date

2018-02-22, 1396/12/03

Actual recruitment end date

2018-03-24, 1397/01/04

Trial completion date

empty

Scientific title

Comparison of the effect of ice massage on the Huko point (LI4) and SP6 on the severity of primary dysmenorrhea of students in two intervention groups and one control group

Public title

Comparison of the effect of ice massage on the Huko point and SP6 on the severity of primary dysmenorrhea of students

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

painful menstrual periods in most menstrual cycles over the past year Pain score of more than 4 based on visual pain assessment scale aged 18 to 28 years, having regular menstruation (Duration of 3 to 7 days and two-twelve days from 21 to 35 days) No history of uterine and pelvic disorders no use of oral contraceptive pills o history of abdominal or pelvic surgery

Exclusion criteria:

smoking in the last six months exercise professionally in the last six months the presence of severe stressors in the last six months Deaths of first-class family members parental divorce non-occurrence of menstruation consumption of more than two dwellings during the study using hot and cold therapy taking herbal drugs to reduce menstrual pain using massage techniques except of the accepted technique of study

Age

From **18 years** old to **28 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is stratified random then students are classified into three groups by block random allocation method.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants: That is, patients are aware of being involved in the study, but not aware of which group they are in at the time of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zabol University of Medical Sciences

Street address

Rajaei Ave, Zabol University of Medical Sciences, Zabol, Iran

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861663335

Approval date

2018-01-22, 1396/11/02

Ethics committee reference number

Zbmu.1.REC.1396.310

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

Primary dysmenorrhoea

Timepoint

Before intervention, After intervention

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: : Ice massage (2 cm in diameter

inside a plastic bag) was performed on Huko spot in a rotary manner daily for 20 minutes until the onset of primary dysmenorrhea.

Category

Treatment - Other

2

Description

Intervention group: Ice massage (2 cm in diameter inside the plastic bag) was performed on spatial 6 in a rotary manner daily for 20 minutes and until the onset of primary dysmenorrhea.

Category

Treatment - Other

3

Description

Control group: In the control group, ice massage (2 cm in diameter inside the plastic bag) was performed on an inapplicable spot (except Huko and SP6) daily for 20 minutes and until the onset of primary dysmenorrhea.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Zabol University of Medical Sciences dormitories

Full name of responsible person
Hosien Shahdadi

Street address
Rajaei Ave, Zabol University of Medical Sciences, Zabol, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Khadijeh Rezaeikahkha

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Rajaei Ave, Zabol University of Medical Sciences, Zabol, Iran

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kh_rezaeikahkha@zbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Zabol University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Hosien Shahdadi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Some part of data
When the data will become available and for how long
Start of access to data from six months after publishing the paper.
To whom data/document is available
Universities.
Under which criteria data/document could be used
for more analysis only for some parts.
From where data/document is obtainable
PI Email: shahdadi@zbmu.ac.ir.
What processes are involved for a request to access data/document
Send email to PI in Email: shahdadi@zbmu.ac.ir.
Comments