

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

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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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kh_rezaeikahkha@zbm.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**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Other areas of specialty/work

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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**Person responsible for updating data****Contact****Name of organization / entity**

Zabol University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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