Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of two methods of acupressure and massage with ice on hoku point on pain intensity

Protocol summary

Study aim
Comparison of the effect of acupressure and ice massage at Hoku point on the severity of dysmenorrhea

Design
Clinical trial with control group, with parallel groups, single blind, randomized with permutation blocks, pilot study on 25 patients

Settings and conduct
Female medical students of Sirjan medical university are the target community. Pain and demographic questionnaire is used. The type of study is single blind. After explaining the procedure, the process of performing ice therapy at the Hoku point on a group of students and acupressure at the Hoku point on another group and an group of ice balls at the adjacent Hoku massage point and the questionnaire will be completed. The researcher, who has already seen the necessary course and training under the supervision of the relevant expert, with moderate pressure of his thumb for 5 minutes in a clockwise direction. 5 minutes counterclockwise stimulates this point. In the acupressure group, only pressure was applied, and in the ice therapy group, pressure was applied to the ice ball at the Hoku point, and in the control group, the ice ball was slowly rotated near the actual Hoku site.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being single, experiencing painful menstruation in previous cycles, age between 18-28 years, no underlying disease Exclusion criteria: interval from menarche time (first menstruation in women) less than 6 months and Having a specific disease or disorder.

Intervention groups
Intervention Group 1: Ice therapy at Hoku Point: Ice therapy at Hoku point: Ice therapy with ice ball at Hoku point between thumb and forefinger Intervention Group 2: Accupressure at Hoku Point:Acupressure at Hoko Point: Massage without Ice Ball at Hoko Point Protrusion between thumb and forefinger Group 3: Control:Use an orb with the appearance of an icy ball near the protrusion of the index finger

Main outcome variables
Dysmenorrhea pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200624047911N1**
Registration date: **2021-02-05, 1399/11/17**
Registration timing: **retrospective**

Last update: **2021-02-05, 1399/11/17**
Update count: **0**

Registration date
2021-02-05, 1399/11/17

Registrant information

Name
Naimeh Pourramezani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 4225 0449

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-05, 1399/04/15

Expected recruitment end date
2020-08-05, 1399/05/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two methods of acupressure and massage with ice on hoku point on pain intensity

Public title

Comparison of the effect of two methods of acupressure and massage with ice on huko point on pain intensity

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Single Experience painful menstruation in previous cycles Age between 18-28 years Regular menstrual cycle Lack of diseases such as hormonal disorders, heart disease, thyroid, diabetes, asthma, kidney disease History of medication such as corticosteroids, painkillers, contraceptives Willingness to cooperate No history of polycystic ovary disease

Exclusion criteria:

Less than 6 months before menarche (first menstruation in women) The patient has cognitive impairment or mental illness History of coagulation disorders.

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: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this pilot study using the method of randomization permutation blocks, 48 samples are randomly assigned in three equal groups. For this purpose, 8 blocks of 6 will be used. Randomization unit: individual Randomization tool: Random number table

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is an interventional study and a randomized clinical trial. This study is a single-blind study in the control group of a plastic ball that is exactly the same ice ball used in the intervention group but at a point close to the point Hoku (outside the main place) massage was applied.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sirjan University of Medical Sciences

Street address

Ebne Sina Street, Sirjan City, Kerman,Iran

City

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Province

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Postal code

7817843153

Approval date

2020-09-13, 1399/06/23

Ethics committee reference number

IR.SIRUMS.REC.1399.029

Health conditions studied

1

Description of health condition studied

dysmenorrhea

ICD-10 code

N94

ICD-10 code description

Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

The severity of menstrual pain is measured on a VAS scale.

Timepoint

Half an hour before the intervention, during the intervention, half an hour after the intervention

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ice therapy at Hoku point

Category

Behavior

2

Description
Intervention group: Massage on the hoku point
Category
Behavior

3

Description
Control group: Ice therapy near Hoku point
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Sirjan School 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
The University of Sirjan
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Naimeh Pourramezani
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Faculty instructor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be used after unidentifying individuals.
When the data will become available and for how long
The access period is 6 months after the publication of the article.
To whom data/document is available
Only researchers
Under which criteria data/document could be used
Similar to the present study
From where data/document is obtainable
Researcher by contact or email
What processes are involved for a request to access data/document
Write a request via email
Comments