Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Effect of pressure on tenth spleen point on pain intensity and amount of bleeding in primary dysmenorrhea

Protocol summary

Summary

Objective:The aim of this study is investigating effect of acupressure on pain severity and amount of bleeding on primery dysmenorrhea Design: This is a semi experimental single blind study which conducted on 100 female residents of Tehran university dormitories suffering from primary dysmenorrhea. Setting and conduct: At First, two of Tehran university dormitories is selected randomly via computerized randomization program as control and intervention groups, then purposive sampling is done. Participants: Participants are all of the female residents of Tehran dormitories whom are eligible for inclusion criteria. Inclusion criteria: aged 18 to 30, single , having regular menstrual period, without any pelvic disease or genital system anomalies. Exclusion criteria: using of oral contraceptive drugs or medications intervene with ovulation cycle, Having sever anxiety and stress during the survey. Research instruments are demographic questionnaire, VAS, and visibility scale Cample and Monoga. One month before the intervention, research instruments are tested in both groups. Intervention: There is no intervention in control group, but just there is usual care. in intervention group, finding tenth spleen point and, how to do pressure is taught in an hour with demonstrating the technique. Then this pressure is done for 4 cycles by samples. Main outcome and major variables: Pain intensity and amount of bleeding is recorded in the period of intervention in both groups. Then all of statics data are analyzed.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201211203037N6**
Registration date: **2014-09-14, 1393/06/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-14, 1393/06/23

Registrant information

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Mehrnaz Geranmayeh
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-01-14, 1391/10/25

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pressure on tenth spleen point on pain intensity and amount of bleeding in primary dysmenorrhea

Public title

Effect of pressure on tenth spleen point on pain intensity and amount of bleeding in primary dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 30 years; menstrual pain intensity based on visual pain scale is grade 1, 2 or 3; unmarried; Having regular menstrual periods (Duration of 3 to 8 days, and the interval between two menstrual periods from 21 to 35 days); Absence of psychological disorders especially depression, moderate and severe (earn points 19 and greater according to Beck Depression Inventory); absence of pain during all cycle or during the time of menstrual bleeding; There is no history of abdominal-pelvic surgery; without any pelvic disease And genital system anomalies; absence of ulceration, varices and inflammatory disease or skin in the area of tenth of splenic. Exclusion criteria: using of oral contraceptive drugs, medications which interfere with ovulation or prostaglandin synthesis inhibitors during the study; any extreme psychological stress during the study.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

by making on accident is computer Among Tehran university dormitories just two of them were selected as a Control group and another intervention group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Ghods street, Keshavarz boulevard, Tehran

City

Tehran

Postal code

-

Approval date

2013-01-27, 1391/11/08

Ethics committee reference number

2765/130/91/د

Health conditions studied

1

Description of health condition studied

dysmenorrhea

ICD-10 code

F45.8

ICD-10 code description

Other somatoform disorders

Primary outcomes

1

Description

Pain intensity in primary dysmenorrhea

Timepoint

Before intervention and 1, 2, 3, 4 Months after intervention

Method of measurement

Pain ruler

2

Description

Amount of bleeding in primary dysmenorrhea

Timepoint

Before intervention and 1, 2, 3, 4 Months after intervention

Method of measurement

Campbell and Mvnga Visual Chart

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

intervention group: in this group during a 30 minute meeting find tenth spleen point and how to do pressure is taught and and technique done. Then this survey is done for 4 cycles by a person who has trained. Pain intensity and amount of bleeding is recorded in this period of time after finishing technique.

Category
Treatment - Other

2

Description
Control group: There is no intervention in control group, but just there is usual care.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitory of Tehran University of Medical Sciences (kooye daneshgah dormitory)
Full name of responsible person
Hamideh Izadi,MS. student of midwifery
Street address
Kooy-e- daneshgah dormitory, North Karegar Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical sciences
Full name of responsible person
Doctor Masoud Younesian
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Central Building of Tehran University of Medical Sciences, Ghods street, Keshavarz boulevard, Tehran
City
Tehran
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, Tehran University of Medical sciences
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
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Person responsible for updating data

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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