Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of acupressure on third liver Point (liv.3) and sixth spleen point (SP.6) on pain intensity for patients with primary dysmenorrhea

Protocol summary

Summary

This study is performed for comparison the effect of acupressure on third liver, sixth spleen and placebo points on primary dysmenorrhea at female dormitory. One hundred and five people will be studied in three cycles. V.A.S. (visual analog scale) tool will be used to assess the pain intensity and those who take four points or more will participate in research. Then the subjects will be divided into three groups randomly: pressure on SP.6, liv.3 and placebo point. In the first menstrual cycle, participants will determine pain intensity at the onset of bleeding and half, 1, 2 and 3 hours later and we will teach them method of applying pressure. The pressure will be applied on both feet alternately as 2 minutes on the pressure point rotating clockwise and 2 minutes rest. Pressure will be applied two times on each leg and a total of four times (a total of 16 minutes). Each time pressure will be stopped with feeling De Chi (i.e. Feeling of tingling, heat, cold, creep) and will be applied on another foot after 2 minutes. In the second and third menstrual cycles, the research unit will apply the pressure herself. Pain intensity will record 0, 0.5, 1, 2, 3 hours after onset of bleeding using V.A.S. scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201308869N1**
Registration date: **2013-05-13, 1392/02/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-13, 1392/02/23

Registrant information

Name
Mahboobeh Kafaei Atrian
Name of organization / entity
Kashan University Of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-05-09, 1391/02/20

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of acupressure on third liver Point (liv.3) and sixth spleen point (SP.6) on pain intensity for patients with primary dysmenorrhea

Public title

Effect of acupressure on dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Being a student at the dormitory, being single, regularity of menses, start of Pain with the onset

of menstrual bleeding, duration of bleeding between 3-8 days and Menstrual intervals of 21-35 days, pain with a score of at least 4 of 10 according to the V.A.S. criteria in most menstrual cycles, lack of pain throughout the all times of menstrual cycle or bleeding, lack of anemia, high blood pressure, Psychiatric disorders especially depression (19 points or more, according to the beck-21 criteria for depression), lack of any known disease of genital tract, secondary dysmenorrhea, no history of abdominal or pelvic surgery, not using tobacco (cigarettes, hookah and drugs) and alcohol, disorders of speech and hearing, mental, heart and renal disorders, respiratory disease, diabetes, asthma, hypothyroidism or hyperthyroidism, severe psychological stress in the past 6 months (e.g., family death, surgery, marriage, separation of parents), lack of voluntary weight loss, absence of any problems in the pressure point such as fractures, ulcers, varicose veins, skin disease or inflammation, specific dietary regimen such as vegetarianism, eating raw, high salt or carbohydrates intake. Exclusion criteria: Use of heat, oral contraceptives or drugs that can affect on ovulation cycle, non steroidal anti-inflammatory, analgesic, Prostaglandins synthesis inhibitors for 4 hours before till 4 hours after applying pressure, not continue to cooperate until the end of the study (3 cycles).

Age
From **17 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study, the research unit is not aware of effectiveness or ineffectiveness of pressure point. Also data analyzer is not aware of intervention and control groups. According to pain scale, blocking randomized allocation will be used to divide the sample study into intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kashan University of Medical Science

Street address
5th of Qotb-e Ravandi Blvd., Kashan University of Medical Science

City
Kashan

Postal code
8715981151

Approval date
2012-01-18, 1390/10/28

Ethics committee reference number
3613/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhoea

ICD-10 code
N-94.4

ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Pain intensity

Timepoint
Pain intensity in the first cycle at the onset of bleeding and half, one, two and three hours after the onset of bleeding. Pain intensity in the second cycle at the onset of bleeding and half, one, two and three hours after the onset of bleeding. Pain intensity in the third cycle at the onset of bleeding and half, one, two and three hours after the onset of bleeding.

Method of measurement
Visual analog scale of pain intensity

Secondary outcomes

1

Description
Quality of life

Timepoint
Before intervention (first cycle) and after intervention (third cycle)

Method of measurement
Quality of life questionnaire (WHOQOL-BREF-26)

Intervention groups

1

Description
Pressure on sp.6 acupressure point. The pressure is applied on both feet alternately as 2 minutes in the pressure point rotating clockwise and 2 minutes rest. Pressure will be applied two times on each leg and a total of four times (a total of 16 minutes). Each time pressure will be stopped with feeling De Chi (i.e. Feeling of tingling, heat, cold, creep) and will be applied on another foot after 2 minutes

Category
Other

2

Description
Pressure on Liv.3 acupressure point. The pressure is applied on both feet alternately as 2 minutes in the pressure point rotating clockwise and 2 minutes rest. Pressure will be applied two times on each leg and a total of four times (a total of 16 minutes). Each time pressure will be stopped with feeling De Chi (i.e. Feeling of tingling, heat, cold, creep) and will be applied on another foot after 2 minutes.

Category
Other

3

Description
Pressure on placebo point. The pressure is applied on both feet alternately as 2 minutes in the pressure point rotating clockwise and 2 minutes rest. Pressure will be applied two times on each leg and a total of four times (a total of 16 minutes). Each time pressure will be stopped with feeling De Chi (i.e. Feeling of tingling, heat, cold, creep) and will be applied on another foot after 2 minutes.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Female Dormitories of Kashan University of Medical Sciences
Full name of responsible person
Tahereh Mazoochi, Ph.D. in Histology, associate professor
Street address
Five kilometers of Ghotbe Ravandi Blvd., Female Dormitories of Kashan University of Medical Sciences
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
5th km of Qotbe Ravandi Blvd., Kashan University of Medical Sciences
City
Kashan
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, Kashan 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
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Kashan University of Medical Sciences
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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