Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of vitamin E and performance of acupressure on point Hegu and mix them together on the severity of dysmenorrhea in adolescent girls.

Protocol summary

Summary

A trial clinical random study based on Solomon design was carried out. At first and after approval of the proposal and securing license from Ethic Committee of Research Department of the university, the authors referred to Bukan Education Organization and received a list of all girls' high schools in the city. Based on economic condition, the schools were categorized in high and low clusters and then the schools were numbered equally likely. Based on random number table, four schools were selected from each cluster. Again, by simple random sampling, from each of the four samples in each cluster, each high school will be assigned to one of the intervention groups: vitamin E, acupressure, vitamin E and acupressure, and one control group. After introduction and a brief discussion about the objectives for the students, they were asked to have a letter of consent signed by their parents. A questionnaire about demographics, personal information, visual analogue scale (VAS), and oral multi-aspect system during dysmenorrhea were given to the participant to fill out. Pain severity of the students before the intervention was measured using the both measurement tools. From the subjects in the both clusters with mediocre level dysmenorrhea who met the inclusion criteria, 25 were selected randomly for each group; totally 50 participant in each treatment group. Subjects in the first group received vitamin E (200 units) two days before and during first three days of menstruation. Subjects in the second group received three times a day acupuncture on Hugo spot (between thumb and index fingers) for 20 mins with 10 mins intervals by initiation of menstruation. Students in the third group (combined intervention) received vitamin E and acupuncture and the students in the fourth group had no medical intervention. Afterward, the subjects were provided with three copies of VAS and verbal multidimensional scale to fill out each one of them during three treatment periods and menstruations. The participants received training in the first introduction meeting about VAS and how to mark the peak level of paint in each period. The collected data was encoded and analyzed in SPSS .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012130214N2**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Hossein Jafarizadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4961

Email address

jafarizadeh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice- President of Urmia University of Medical Sciences.

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date
2017-04-19, 1396/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of vitamin E and performance of acupressure on point Hegu and mix them together on the severity of dysmenorrhea in adolescent girls.

Public title
Comparison of the effect of vitamin E and performance of acupressure and mix them together on the severity of dysmenorrhea in adolescent girls.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Unmarried and age range 14-18; Regular menstruation with 21-35 days interval with early dysmenorrhea with mediocre severity based on visual analogue scale; Pain starting few hours before menstruation and lasts until the fifth day; No chronic disease; No symptom of itching, irritation, abnormal vaginal secretion or any special women's disease; Not using drugs like contraceptive and anti-inflammations; No stressors (divorce, loss of blood relatives) in past six months; No special diet (vegetarian, raw vegetarian); Desire to participate; No fracture and inflammation in acupunture point hegu. Exclusion criteria: Leaving the study for whatever reason; Development of the stressors noted in inclusion criteria; Development of any type of disease that needs long-term or permanent drug/food supplements/vitamin intervention; Irregular use of medical intervention throughout the study; Fracture and inflammation at the acupoint.
Age
From **14 years** old to **18 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Solomon four-group design

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Scienses
Street address
Adjacent to the 115 emergency, Jahad Avenue, University Headquarters, Urmia
City
Urmia
Postal code
Approval date
2016-10-26, 1395/08/05
Ethics committee reference number
Ir.umsu.rec.1395.319

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 dysmenorrea
Timepoint
Before and three months after intervention
Method of measurement
Visual analogue scale and Verbal multidimensional system

Secondary outcomes

1

Description
The duration of dysmenorrhea
Timepoint
In three consecutive menstrual cycles
Method of measurement
In hours

Intervention groups

1

Description
Intervention one: The first group of participants (vitamin E) two days before menstruation and first three days of menstruation on a daily basis vitamin E (200 IU) is given in three consecutive menstrual cycles.
Category
Prevention

2

Description
Intervention two: After onset of menstruation, hego point (between the index and thumb) will be pressed three time a day in three cycles (20 min accupressure and 10 min rest).
Category
Prevention

3

Description
Intervention three: Participants will receive a combination of both vitamin E and acupressure.
Category
Prevention

4

Description
Control group: In this group there will be no intervention.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Education Organization of Bukan city
Full name of responsible person
Masoumeh karimi
Street address
Education Management Organization, Shahid Bahonar Blvd
City
Bukan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Urmia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Staff of Urmia University of Medical Sciences, Emergency district, Resalat Blvd, Urmia
City
Urmia
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, Urmia 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
Urmia University of Medical Sciences
Full name of responsible person
Hossein Jafarizadeh
Position
Master of Science in Nursing, Head of Community Health Nursing Departmen
Other areas of specialty/work
Street address
Nursing and Midwifery Faculty, Nazloo highway,Urmia
City
Urmia
Postal code
Phone
+98 44 3275 4963
Fax
Email
JAFARIZADEH@UMSU.AC.IR
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Hossein Jafarizadeh
Position
Master of Science in Nursing, Head of Community Health Nursing Department
Other areas of specialty/work
Street address
Nursing and Midwifery Faculty, Nazloo highway,Urmia
City
Urmia
Postal code

Phone
+98 44 3275 4963
Fax
Email
JAFARIZADEH@UMSU.AC.IR
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Hossein Jafarizadeh
Position
Master of Science in Nursing, Head of Community Health Nursing Department
Other areas of specialty/work
Street address
Nursing and Midwifery Faculty, Nazloo highway,Urmia
City
Urmia
Postal code

Phone
+98 44 3275 4963
Fax
Email
JAFARIZADEH@UMSU.AC.IR
Web page address

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