

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effect of vitamin E and performance of acupuncture 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, acupuncture, vitamin E and acupuncture, 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 pain 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

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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 acupuncture 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 Sciences

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

lr.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 dysmenorrhea

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 Department

Other areas of specialty/work

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empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty