

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrual syndrome

Protocol summary

Summary

Present study will be conducted to compare the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrual syndrome. This study is a clinical trial. female students who live at university dorm will be randomly selected and allocated into two groups of 46. Inclusion criteria: 18 to 35 year old; having regular menstruation cycles with equal intervals (21- 35 days); not having a history of psychological or chronic physical diseases; Not having a history of using anti-depressant; hormonal drugs and also drugs that have interactions with vitamin B6 and not having any kind of mass, infection or scar on the external ear. Exclusion criteria: Occurrence of any undesirable incidence or death; not presenting all the auriculotherapy sessions correctly and completely; not pressuring the seeds in the auriculotherapy group and not completing the table of symptoms' severity recordings .The first group will receive auriculotherapy (10 sessions) for 2 menstrual cycles and the second group will consume 40 mg of vitamin B6 daily from a week prior to their menstruation for 2 menstrual cycles. The severity of symptoms will be recorded for both groups during two cycles before the intervention and two cycles after the intervention. Data gathering tool is a questionnaire with 28 questions.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201509182889N5**

Registration date: **2017-01-09, 1395/10/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-09, 1395/10/20

Registrant information

Name

Mahboubeh Valiani

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-04-30, 1394/02/10

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrual syndrome

Public title

Comparing the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 35 year old; having regular menstruation cycles with equal intervals (22 to 35 days);

having 5 signs of pms in last 2 months; normal BMI ; not having a history of psychological or chronic physical diseases and depression; Not having a history of using anti-depressant; sedatives and hormonal drugs and also drugs that have interactions with vitamin B6 and not having any kind of mass, infection or scar on the external ear . Exclusion criteria: Occurrence of any undesirable incidence or death; not presenting all the auriculotherapy sessions correctly and completely (more than 2 consecutive absences);not pressuring the seeds in the auriculotherapy group and not completing the table of symptoms' severity recordings would cause the participants to be excluded.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sealed envelope method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences and Health Services

Street address

Isfahan university of Medical sciences

City

Isfahan

Postal code

319081775

Approval date

2015-07-22, 1394/04/31

Ethics committee reference number

ir.mui.rec.1394.394342

Health conditions studied

1

Description of health condition studied

premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

premenstrual tension syndrome

Primary outcomes

1

Description

premenstrual syndrome(edema, low back pain,low abdominal pain,mastalgia,...)

Timepoint

Before of intervention, 1,2,month after intervention

Method of measurement

DSM-IV questionnaire

Secondary outcomes

1

Description

General health-Depression-Anxiety

Timepoint

preintervention -1 and 2month after intervention

Method of measurement

GHQ(28) and Beck questionairs

Intervention groups

1

Description

Intervention group 1: the auriculotherapy will be executed in 10 weekly sessions during 2 menstruation cycles (except for the 7 days of menstrual bleeding). Each session will be lasted about 20 minutes and will be conducted by the researcher at the dorm in a private place that will be considered for this matter. At each session Shenmen, zero, endocrine, ovary, womb, adrenal, kidney, external genitalia, liver, brain and brainstem points will be stimulated. At the end of each session herbal seeds will be placed on specified points and will be remained for at least 3 days; seeds will be pressured by the participant for a whole minute every hour except for the time of sleep. Phone calls will be made for reminding.

Category

Treatment - Other

2

Description

Intervention group 2: They will take Vitamin B6 (40 mg) (made by Iran Hormone Company), daily from one week before starting of menstrual bleeding. This group will continue the consumption of B6 during the two months

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Dorms of Isfahan university of Medical sciences

Full name of responsible person

reza ghasemi

Street address

Isfahan university of Medical sciences

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Research Department of Medical Sciences

Full name of responsible person

Mehdi Nemathbakhsh

Street address

Isfahan University of Medical Sciences, Hezar jereb street, Esfaha

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan Research Department 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

Isfahan University of Medical Sciences

Full name of responsible person

sharareh koleini

Position

MS

Other areas of specialty/work

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Person responsible for scientific inquiries

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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