Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effect of auriculotherapy and vitamin B6 on the symptoms of premenstrul 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
Iran (Islamic Republic of)
Phone
+98 31 3651 4640
Email address
valiani@nm.mui.ac.ir

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 premenstrul 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 tention 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 questionnair

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
Intervantion 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

Treatment - Drugs

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 universityof 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

Street address
Isfahan University of Medical Science, Hezar jereb street, Shiraz Gate

City
Isfahan

Postal code
8199939438

Phone
+98 31 3792 2936

Fax

Email
sharareh_Koleini@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan university of medical sciences

Full name of responsible person
Mahboube Valiani

Position
Isfahan university of medical sciences

Other areas of specialty/work

Street address
Ms

City
Isfahan of university of medical sciences

Postal code
8199939438

Phone
+98 31 3792 2936

Fax

Email
valiani@nm.mui.ac.ir

Web page address
mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Isfahan university of medical sciences

Full name of responsible person
Sharareh_Koleini

Position
Ms

Other areas of specialty/work

Street address
Isfahan University of Medical Science, Hezar Jereb Street, Shiraz Gate, Isfahan

City
Isfahan university of medical sciences

Postal code
8173785737

Phone
+98 31 3626 3804

Fax

Email
sharareh_koleini@yahoo.com

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