Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of ear acupressure on premenstrual syndrome

Protocol summary

Summary

This study will be conducted with the aim of determining the effect of auriculotherapy on premenstrual syndrome in female students residing in dormitories of Mashhad University of Medical Sciences. This study is a three-group clinical trial. The subjects will be assigned randomly to three groups of 60; that is, a seed and a non-seed auriculotherapy group and a negative control group. From six days before to four days after the onset of menstruation, pressure must be applied on the seed four times a day for one minute each time. The premenstrual syndrome symptoms severity questionnaire will be completed in both groups two months before and two months after the intervention. inclusion criteria: being aged between 20 and 40 years; regular menstrual period(with equal intervals of 21 to 35 days); presence of at least five symptoms of premenstrual syndrome in the last two months; and normal body mass. exclusion criteria: having a history of physical and psychological diseases and depression; having a history of consuming antidepressants, sedatives, or hormonal drugs; presence of any mass, inflammation, infection, or injury in the outer ear in the auriculotherapy group; unwillingness to continue the cooperation, or death; and failure to fill out the daily symptoms table correctly and completely(as described).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050921934N3**
Registration date: **2017-08-21, 1396/05/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-21, 1396/05/30

Registrant information

Name
Sedigheh Sheidaei
Name of organization / entity
Mashhad University Of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 25 3774 7244
Email address
sheidaeis931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-05-09, 1396/02/19

Expected recruitment end date

2017-12-10, 1396/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ear acupressure on premenstrual syndrome

Public title

The effect of ear acupressure on premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being aged between 20 and 40 years; regular menstrual period(with equal intervals of 21 to 35 days); presence of at least five symptoms of premenstrual syndrome in the last two months; and normal body mass. Exclusion criteria: having a history of physical and psychological diseases and depression; having a history of consuming antidepressants,

sedatives, or hormonal drugs; presence of any mass, inflammation, infection, or injury in the outer ear in the auriculotherapy group; unwillingness to continue the cooperation, or death; and failure to fill out the daily symptoms table correctly and completely(as described).

Age
From **20 years** old to **39 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Science

Street address
Deputy of Research and Technology, After Hoveyze Cinema, Daneshgah street, Mashhad University of Medical Science, Mashhad

City
Mashhad

Postal code

Approval date
2017-05-07, 1396/02/17

Ethics committee reference number
IR.MUMS.REC.1396.24

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
2 months before treatment and 2 months after treatment

Method of measurement
DSM-IV questionnair

Secondary outcomes

1

Description
Depression

Timepoint
2 months before treatment and 2 months after treatment

Method of measurement
Beck questionairs

Intervention groups

1

Description
Intervention Groups: trained 6 days before to 4 days after the onset of menstruation on seeds in the liver, the kidneys, the base of the brain, gastric, ovarian and uterine pressure 4 times a day, each time one minute

Category
Treatment - Other

2

Description
The intervention group without SID: trained 6 days before to 4 days after the onset of menstruation-free adhesives Sayed without pressure on the liver, the kidneys, the base of the brain, gastric, ovarian and uterine install.

Category
Other

3

Description
Control: no intervention is not performed.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Girls dormitories of Mashhad University of Medical Sciences

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Science

Full name of responsible person

Dr Saieed Eslami

Street address

Deputy of Research and Technology, After Hoveyze Cinema, Daneshgah street, Mashhad University of Medical Science, Mashhad

City

Mashhad

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, Mashhad University of Medical Science

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

Mashhad University of Medical Sciences

Full name of responsible person

Farzane Jafar Nejad

Position

Master of Midwifery

Other areas of specialty/work

Street address

Ibn Sina Street، Doctoora intersection

City

Mashhad

Postal code

Phone

+98 51 3859 1511

Fax

Email

JaafarnejadF@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzane Jafar Nejad

Position

Master of Midwifery

Other areas of specialty/work

Street address

Ibn Sina Street، Doctoora intersection

City

Mashhad

Postal code

Phone

+98 51 3859 1511

Fax

Email

JaafarnejadF@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Sedigheh Sheidaei

Position

Graduate Student Midwives

Other areas of specialty/work

Street address

Ibn Sina Street, Doctora intersection

City

Mashhad

Postal code

Phone

+98 51 3859 1511

Fax

Email

sheidaeis931@mums.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*