

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

An Investigation of the Effect of Auriculotherapy on Menstrual Irregularity Caused by PCOS in 18-35-Year-Old Unmarried Girls in Isfahan in 2012

Protocol summary

Summary

This study aims at determining the effect of auriculotherapy in patients with PCOS. Study's inclusion criteria are: 18-35-year-old unmarried girls with PCOS according to the Rotterdam criteria and at least one healthy ear who did not have a history of systemic, endocrine and nervous diseases, addiction or hyperprolactinemia and did not use any specific medication. Study's exclusion criteria include: drug treatment during auriculotherapy, independent drug discontinuation, failure to refer for completing the treatment (if auriculotherapy group members did not refer for two sessions, they were excluded from the study. The seed is preserved for 4 days and its effect remains 72 hours after its removal) and the consumption of any hormone and psychiatric medications. This is a clinical trial study conducted on sixty 18-35-year-old unmarried girls with clinical, laboratory and ultrasonography symptoms. Samples were randomly divided into auriculotherapy and drug treatment groups who were under treatment for 2 and 3 months, respectively. Clinical symptoms in both groups were investigated in 3 steps. Research data was collected via observation, laboratory investigation and ultrasonography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091614682N1**
Registration date: **2013-12-21, 1392/09/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-21, 1392/09/30

Registrant information

Name

Imaneh Khaki

Name of organization / entity

Isfahan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

0098

Email address

i_khaki@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An Investigation of the Effect of Auriculotherapy on Menstrual Irregularity Caused by PCOS in 18-35-Year-Old Unmarried Girls in Isfahan in 2012

Public title

Effect Of Ear Acupuncture On PolyCystic Ovarian Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Study's inclusion criteria are: 18-35-year-old unmarried girls with PCOS according to the Rotterdam criteria and at least one healthy ear who did not have a history of

systemic, endocrine and nervous diseases, addiction or hyperprolactinemia and did not use any specific medication. Study's exclusion criteria include: drug treatment during auriculotherapy, independent drug discontinuation, failure to refer for completing the treatment (if auriculotherapy group members did not refer for two sessions, they were excluded from the study. The seed is preserved for 4 days and its effect remains 72 hours after its removal) and the consumption of any hormone and psychiatric medications.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan university of Medical Sciences

Street address

Isfahan, Square Azadi

City

Isfahan

Postal code

Approval date

2012-11-07, 1391/08/17

Ethics committee reference number

391314

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

E28.2 Polycystic ovarian syndrome

Primary outcomes

1

Description

Irregular Mense

Timepoint

Before the intervention, one month after the intervention, two months after the intervention, immediately after intervention, after intervention in three dimensions

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group Auriculotherapy / every other day / 20 sessions / 2 month / ten sessions after each menstrual cycle

Category

Treatment - Other

2

Description

medications / every day / three months / types of drugs used in the treatment of polycystic ovary syndrome

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic Mother Mehr

Full name of responsible person

Mahbobeh Valiani

Street address

Mehre Mader Clinic, Third Floor, Azadi Center, between Banks Eghtesade Novin and Day, Azadi Square, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan university of Medical Sciences

Full name of responsible person

Maryam Kianpour

Street address

School of Nursing and Midwifery, Medical Sciences,
Azadi Square, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

391314

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

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Mahboubeh Valiani

Position

Master

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Isfahan university
ofMedical Sciences, Isfahan, Iran.

City

Isfahan

Postal code

Phone

+98 31 1668 0042

Fax

Email

valiani@nm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

Mahboubeh Valiani

Position

Masters

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Isfahan university
ofMedical Sciences, Isfahan, Iran.

City

Isfahan

Postal code

Phone

+98 31 1668 0042

Fax

Email

valiani@nm.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

imaneh khaki

Position

Master Students

Other areas of specialty/work

Street address

No. 14, Alley 22, Shahid Bahonar Street, Khomeini
Town, Qom

City

Qom

Postal code

Phone

+98 25 3270 2630

Fax

Email

imanekhaki@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