Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of auriculotherapy on the hormonal and clinical indicators of infertile women with polycystic ovary syndrome (PCOS)

Protocol summary

Study aim

Determining the effect of auriculotherapy on hormonal and clinical indicators of infertile women with polycystic ovary syndrome

Design

A double-blind, two-group, randomized clinical trial with random selection from the envelopes corresponding to the numbers of the intervention and placebo groups on 70 participants.

Settings and conduct

Participants in the intervention group will be treated over 3 menstrual cycles in a private room at a clinic in Isfahan, starting after the end of bleeding for 12 sessions (4 sessions every 5 days). Points on the pituitary, ovaries, uterus, pelvis, endocrine system, master shoulder, Shen Men, thalamic, and relax will be stimulated using a Plus Excel 2 pointer followed by a seed, and patients should press the seeds for one minute every hour. The placebo group will receive non-functional device stimulation and false seed stimulation without pressure. After the intervention, questionnaires will be given again to both groups.

Participants/Inclusion and exclusion criteria

primary infertility, NL spermogram, no use of clomiphene or letrozole, ovulatory dysfunction, no uterine abnormalities, no uncontrolled underlying conditions, BMI 18.5- 29.9, no use of medications or complementary methods in the past 3 months, , no inflammation in the ears, and depression, anxiety, and stress scores below 21, 15, and 26, respectively.

Intervention groups

In the intervention group, participants receive auriculotherapy for 12 sessions over 3 menstrual cycles. In the placebo group, points are stimulated with a non-functional device without pressure and are falsely stimulated.

Main outcome variables

Duration of menstrual cycle; Hirsutism; Acne; Menstrual irregularity; Mean levels of sex hormones (E2, DHEAS, free Testosterone, Total Testosterone, FSH, LH, AMH); Mean ultrasound findings (number of follicles, follicle size, ovary size, endometrial thickness); βHCG.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091219002889N15**
Registration date: **2024-11-06, 1403/08/16**
Registration timing: **prospective**

Last update: **2024-11-06, 1403/08/16**
Update count: **0**

Registration date

2024-11-06, 1403/08/16

Registrant information

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-09, 1403/08/19

Expected recruitment end date

2025-05-09, 1404/02/19

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of auriculotherapy on the hormonal and clinical indicators of infertile women with polycystic ovary syndrome (PCOS)

Public title
effect of auriculotherapy on the hormonal and clinical indicators of infertile women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Couple's desire to get pregnant Primary infertility Normal spermogram Not taking drugs such as clomiphene citrate and letrozole Infertility due to ovulation disorder Absence of structural and anatomical disorders of the uterus such as polyps, myomas, malformations of the Müllerian system, etc. Not suffering from any uncontrolled underlying disease (diabetes, hypertension, lupus, etc.) 18.5-29.9= BMI Failure to use certain drugs (hormonal drugs, drugs related to the underlying disease) during the last three months Non-use of complementary and alternative medicine methods and traditional medicine during the last three months No addiction Absence of any mass, inflammation, or infection in the ears The scores of depression, anxiety, and stress are less than 21, 15, and 26, respectively
Exclusion criteria:
Secondary infertility Abnormal spermogram Taking any medication related to the underlying disease and hormonal treatments during the last 3 months Infertility with causes other than ovulation disorders Suffering from structural and anatomical disorders of the uterus such as polyps, myomas, malformations of the Müllerian system, etc. Having any uncontrolled underlying disease (diabetes, hypertension, lupus, etc.) BMI>30 Application of complementary and alternative medicine methods and traditional medicine during the last three months Presence of any mass, inflammation, or infection in the ears
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, envelopes are used in the following manner: an equal number of identical envelopes in design and material are prepared corresponding to the number of participants in the study. Then, even and odd numbers (from 1 to 70) are written inside each envelope. Envelopes containing even numbers are assigned to the auriculotherapy group, while envelopes with odd numbers are assigned to the placebo group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, double-blinding means that neither the participants nor the individual collecting the data are aware of the allocation of patients to the intervention or placebo groups. This process is carried out as follows: a trained individual independent of the research team is responsible for distributing and collecting the questionnaires and scoring them. During the allocation phase, sealed envelopes containing even and odd numbers are randomly given to the patients. Even numbers indicate assignment to the auriculotherapy group, while odd numbers indicate the placebo group. These envelopes are distributed only by the trained individual, and their contents remain unknown to both the participants and the data collector. This method ensures that none of the parties involved in the study know which patient belongs to which group, preventing any potential bias and ensuring impartiality and accuracy in the results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Biomedical Research Ethics System
Street address
Hazarjarib Street, Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2024-10-16, 1403/07/25
Ethics committee reference number
IR.MUI.REC.1403.030

Health conditions studied

1

Description of health condition studied
PCOS
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Length of menstrual cycle
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
day

2

Description
hirsutism
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
Ferriman-Gallwey Score

3

Description
Acne
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
Global Acne Grading System

4

Description
Menstrual irregularity
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
Questionnaire (yes-no)

5

Description
E2 hormone
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ELISA (pg/mL)

6

Description
Dehydroepiandrosterone Sulfate hormone
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ELISA (µg/dL)

7

Description
Free Testosterone hormone
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ELISA (pg/mL)

8

Description
Total Testosterone hormone
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ELISA(ng/dl)

9

Description
Follicle Stimulating Hormone
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ELISA(IU/L)

10

Description
Luteinizing Hormone
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ELISA(IU/L)

11

Description
Anti-Müllerian Hormone
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ELISA(ng/ml)

12

Description
Number of follicles

Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ultrasound (number)

13

Description
Follicle size
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ultrasound (number (mm))

14

Description
Ovary volume
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ultrasound(cm^3)

15

Description
Endometrial thickness
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
ultrasound(mm)

16

Description
Beta-Human Chorionic Gonadotropin
Timepoint
After completing the intervention
Method of measurement
ELISA(mIU/mL)

Secondary outcomes

1

Description
stress
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
DAS-21 (Depression Anxiety Stress)

2

Description
Anxiety
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
DAS-21 (Depression Anxiety Stress)

3

Description
Depression
Timepoint
Before the intervention, immediately and three months after the intervention
Method of measurement
DAS-21 (Depression Anxiety Stress)

Intervention groups

1

Description
Intervention group: In this study, auriculotherapy is used as a non-invasive and side-effect-free treatment method. This approach is based on stimulating specific points on the ear using the "Pointer Plus Excel II" device and placing seeds on these points. The stimulated points include the pituitary, ovary, uterus, pelvis, endocrine, master shoulder, Shen Men, thalamic, relax, and ectoderm points. By stimulating these points, signals are sent to the brain to regulate the body's physiological functions.The auriculotherapy session schedule consists of three menstrual cycles. Starting from the end of menstrual bleeding, each cycle includes four auriculotherapy sessions (every five days), with a total of 12 sessions for each participant. The seeds remain on the ear points for five days and are replaced during the participants' next visit.Participants are advised to press the seeds for one minute every hour throughout the day (except during sleep) to maximize the stimulation effects. Showering while the seeds are on the ears does not interfere with treatment, and reminder calls may be made to encourage participants to press the seeds regularly.After completing the auriculotherapy sessions, assessments (covering clinical, hormonal, and sonographic symptoms of PCOS, as well as depression, stress, and anxiety) are conducted immediately after the intervention and again three months post-intervention.
Category
Treatment - Other

2

Description
Control group: In the placebo group, points are stimulated falsely without activating the device (and without pressure from the device on the points), and then treated without actual stimulation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Hospital Clinic
Full name of responsible person
Tahereh Heydarian
Street address
ebn Sina St
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amin@mui.ac.ir

2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital Clinic
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Al-Zahra Hospital Clinic
Full name of responsible person
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4

Recruitment center
Name of recruitment center
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5

Recruitment center
Name of recruitment center
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6

Recruitment center
Name of recruitment center
Amir Hamze Health Center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Tahereh Heydarian
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Midwifery master's student
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main results of the study will be shared.

When the data will become available and for how long

Data access starts 6 months after results are published.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For the knowledge and use of other researchers in their next similar studies

From where data/document is obtainable

For correspondence regarding this study, please contact the responsible individual, Dr. Valiani, via email at valiani@nm.mui.ac.ir.

What processes are involved for a request to access data/document

After sending the request from the applicant, the email will be checked and after confirming the purpose of accessing the data, the responsible person will respond to the request as soon as possible.

Comments