

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of acupressure on quality of life in patients with polycystic ovarian syndrome

Protocol summary

Study aim

The effect of acupressure on quality of life in patients with pcpos

Design

Clinical trials with control group, with parallel groups, randomized

Settings and conduct

Study Type: Clinical Trial Sample number: 96 people
Sample collection site: Women's specialized gynecology clinic located in Yasuj Mofattah Clinic Data gathering tool: Clinical signs checklist, Laboratory biomarkers and correctional version of the quality of life questionnaire related to health of polycystic ovary syndrome, 12 questions of quality of life questionnaire Mode of intervention: Split the samples into acupressure group and acupressure pseudo group Data Measurement: Before intervention, three months after intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria Confirmation of pcpos by gynecologist; Marriage; Age 45 to 15 years; Achieving minimum score (1/3 score of quality of life correction questionnaire related to polycystic ovary syndrome), Quality of life questionnaire 12 questions, minimum score 12 to 24; Absence of male infertility (confirmed by spermogram test); Exclusion criteria: Suffering from any systemic or endocrine and neurological diseases, including: cardiovascular disease, type 1 and 2 diabetes, use of any hormonal drug except clomiphene, hookah and alcohol and smoking addiction according to the research unit, no infertility Male (confirmed by spermogram test)

Intervention groups

Group (A): The subject's group of acupressure points with clomiphene Group(B): Group of Acupuncture Pseudo-Pseudoephedrons with Clomiphene

Main outcome variables

Improving the quality of life of patients with polycystic ovary syndrome

General information

Reason for update

Applying the opinions of respected professors and judges after the intervention and the defense session

Acronym

IRCT registration information

IRCT registration number: **IRCT20180725040587N1**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-01, 1400/08/10**

Update count: **1**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Marzieh Nekooi Nematollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7230

Email address

nekooim@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-12, 1397/05/21

Expected recruitment end date

2018-09-12, 1397/06/21

Actual recruitment start date

2018-08-12, 1397/05/21

Actual recruitment end date

2018-10-13, 1397/07/21

Trial completion date

2018-10-13, 1397/07/21

Scientific title

The effect of acupressure on quality of life in patients with polycystic ovarian syndrome

Public title

The effect of acupressure on quality of life in patients with polycystic ovarian syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

By the gynecologist, polycystic ovarian syndrome has been confirmed Marital status Earning the minimum basic score (1.3 points for the correction version of the quality of life questionnaire related to health of polycystic ovary syndrome), Quality of life questionnaire 12 questions, minimum score 24-12 Absence of male infertility (confirmed by spermogram test) Having ages 45-15 years

Exclusion criteria:

Having any systemic or endocrine and neurological disease based on the patient's question including: cardiovascular disease, type 1 and type 2 diabetes, neoplastic diseases including Cushing's syndrome, congenital adrenal hyperplasia and hyperprolactinemia (approved by a specialist) Addiction to hookah, cigarettes, drugs and alcohol according to the research unit Taking any hormonal medication except clomiphene Presence of male infertility (confirmed by spermogram test)

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **96**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using software Sample Randomizer

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be blind-doubled. In this way, patients will be blinded according to the type of intervention. Patients participating in the study will not know whether the pressure points are real acupressure points or false points. Also statistical analyst about the data of the intervention group (real points of acupressure) and the control group (false points of acupressure) Will not know.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Yasouj University of Medical Sciences

Street address

Yasuj-Shahid Motahari Blvd.-Yasouj University of Medical Sciences

City

Yasouj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2018-07-20, 1397/04/29

Ethics committee reference number

IR.YUMS.REC.1397.035

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Quality of Life in Patients with Polycystic Ovary Syndrome

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Modified Polycystic Ovary Syndrome Health-Related Quality Of Life Questionnaire (MPCOSQ) ,Short Form12 (SF-12)

Secondary outcomes

1

Description

Hirsutism

Timepoint

Before intervention, three months after the intervention
Method of measurement
Friedman Galway Scale

2

Description

Acne

Timepoint

Before intervention, three months after the intervention

Method of measurement

Global Acne Grading System (GAGS)

3

Description

Alopecia

Timepoint

Before intervention, three months after the intervention

Method of measurement

Ludwig scale

4

Description

Total Testosterone

Timepoint

Before intervention, three months after the intervention

Method of measurement

NG/L

Intervention groups

1

Description

Intervention group: Intervention in group A (real points of acupressure) for a month and a half (equivalent to 12 sessions) twice a week, each session for one hour (each point 5 minutes including points REN-3, REN-4, IV3 L, SP10, (SP6) and will start with the amount of pressure to the extent that the pressure point is anesthetized. The location of acupressure points and false points will be determined by a laser point detector.

Category

Lifestyle

2

Description

Control group: intervention in group B (false points of acupressure), for a month and a half (equivalent to 12 sessions) twice a week, each session for one hour (each point 5 minutes including points REN-3, REN-4, IV3 L, SP10, SP6) and will start with the amount of pressure to the extent that the pressure point is anesthetized. The location of acupressure points and false points will be determined by a laser point detector

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Specialty Clinic located in the martyr Mohfat Clinic affiliated to Yasouj University of Medi

Full name of responsible person

Dr. Bahram Mohammadi

Street address

Golestan No. 10,60 Metro Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr Hossein Marie ouriad

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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

Yasouj 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

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hosseinichenar@yahoo.com

Person responsible for general inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Doctor Naza Afrin Hosseini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Student

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Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available