

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison acupuncture with Clomiphene for ovulation induction in polycystic ovary syndrome

Protocol summary

Study aim

To compare the effectiveness of acupuncture with clomiphene in stimulating ovulation in infertile women with polycystic ovary syndrome

Design

Clinical trial with control group, parallel, single-blind, randomized, on 110 patients with simple randomization.

Settings and conduct

Clinical trial on infertile PCOS patients referred to women's clinic of Imam Reza Hospital and Milad Infertility Center, Mashhad, Iran Acupuncture (real or sham) for up to 3 cycles, twice a week Clomiphene (real or placebo) at a daily rate of 50, 100 and 150 mg in the first to third cycle of treatment from the third day of the cycle for 5 days Evaluation based on serial vaginal ultrasound in each cycle in terms of follicle growth and proof of ovulation In this study, patients were blinded to the type of treatment. Also, gynecologist, statistical analyst and research assistant (interrogator) were blinded to the study groups. Only the acupuncturist was aware of patients' groups.

Participants/Inclusion and exclusion criteria

Inclusion conditions: age between 20 and 40 years; suffering from infertility and polycystic ovary syndrome according to the Rotterdam criteria. Conditions of non-inclusion: simultaneous presence of other endocrine, hepatic and renal disorders; taking hormonal or herbal medicines containing hormones during the last three months; pregnancy, miscarriage or childbirth in the last 6 months; history of thromboembolism; drug dependence; Uncontrolled blood pressure

Intervention groups

intervention group (real acupuncture + clomiphene placebo) control group (real clomiphene + sham acupuncture)

Main outcome variables

Primary endpoint: ovulation rate in two groups
Secondary outcomes: the number of developing follicles (greater than or equal to 14 mm) and mature follicles

(greater than or equal to 18 mm); Adverse events

General information

Reason for update

We decided to include the actual day patients entered the study

Acronym

IRCT registration information

IRCT registration number: **IRCT201512057265N3**

Registration date: **2015-12-23, 1394/10/02**

Registration timing: **prospective**

Last update: **2023-06-28, 1402/04/07**

Update count: **1**

Registration date

2015-12-23, 1394/10/02

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Mashhad University of Medical Sciences

Expected recruitment start date

2015-12-13, 1394/09/22

Expected recruitment end date

2016-05-11, 1395/02/22

Actual recruitment start date

2015-12-25, 1394/10/04

Actual recruitment end date

2016-07-24, 1395/05/03

Trial completion date

2016-10-30, 1395/08/09

Scientific title

Comparison acupuncture with Clomiphene for ovulation induction in polycystic ovary syndrome

Public title

Comparison acupuncture with Clomiphene for ovulation induction in polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with infertility and polycystic ovary syndrome

Exclusion criteria:**Age**

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Actual sample size reached: **77**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients were blinded to the type of treatment. Also, the gynecologist, statistical analyst and research assistant (interrogator) were blinded to the study groups. Only the acupuncturist was informed of the patients' groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Mashhad University of Medical Sciences

Street address

MUM's central office, Daneshgah street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2015-12-01, 1394/09/10

Ethics committee reference number

IR.MUMS.fm.REC.1394.346

Health conditions studied**1****Description of health condition studied**

Polycystic Ovary Syndrome

ICD-10 code

F28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Ovulation

Timepoint

Every three days since subjects entered the study

Method of measurement

Serial vaginal ultrasonography

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: sham acupuncture + clomiphene

Category

Treatment - Other

2**Description**

Intervention group: Real acupuncture + placebo

Clomiphene

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr Leili Hafizi Lotfabad

Street address

Gynecology clinic, Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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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

Mashhad 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**

Department of Gynecology, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Hamideh Azizi

Position

Gynecology resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Other areas of specialty/work

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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