Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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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Iran (Islamic Republic of)

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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 Lotfabadi

Street address
Gynecology clinic, Imam Reza Hospital

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Sponsors / Funding sources

1

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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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Ph.D.

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Person responsible for updating data

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Other areas of specialty/work

Acupuncture

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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