

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effects of acupuncture on outcome of in vitro fertilization and intracytoplasmic sperm injection (IVF/ICSI) in women with polycystic ovarian

Protocol summary

Summary

Acupuncture as a traditional method has beneficial effects on physiological systems, anxiety reduction, and quality of life enhancement. However, scientific rationales for this approach within in vitro fertilization and intracytoplasmic sperm injection (IVF/ICSI) have not been absolutely accepted. The aim of this study was to investigate the effects of acupuncture on IVF/ICSI outcome in women with polycystic ovarian (PCO) and comparing it with placebo acupuncture. Patients who had uncontrolled systemic disorders, ovum or embryo donor, other infertility factors exception PCO, and who for personal reasons did not want to participate further were excluded from the study. In this triple blind study sixty-two women with PCO admitted to the clinic for treatment of infertility were randomly invited to participate (31 women were randomly set into the acupuncture group and 31 women were set into the control placebo group) between June 2009 to September 2010. Acupuncture was performed in 5 sessions of thirty minutes. Accordingly, in the acupuncture group, traditional Chinese medicine and in the placebo group based on wrong location the same needles were used. The results were followed 2, 4, and 18 weeks after embryo transfer, and postpartum (miscarriage, Take home baby, Oocyte metaphase II rate, fertilization and embryo quality).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011275181N4**

Registration date: **2011-04-13, 1390/01/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-13, 1390/01/24

Registrant information

Name

Batool Rashidi

Name of organization / entity

Vali E Asr Reproductive Health Research Center

Country

Iran (Islamic Republic of)

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+98 21 6693 9320

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Recruitment status

Recruitment complete

Funding source

Shayamehr clinic in Tehran

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-09-22, 1389/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of acupuncture on outcome of in vitro fertilization and intracytoplasmic sperm injection (IVF/ICSI) in women with polycystic ovarian

Public title

Effects of acupuncture on outcome of in vitro fertilization and intracytoplasmic sperm injection (IVF/ICSI) in women with polycystic ovarian

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with the diagnosis of PCO (Rotterdam criteria) admitted to the clinic for IVF or ICSI treatments of infertility . Exclusion criteria: Patients who had uncontrolled systemic disorders, ovum or embryo donor, other infertility factors exception PCO, and who for personal reasons did not want to participate further were excluded from the study.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 62

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical faculty, Tehran University of Medical Sciences

Street address

Tehran Medical Faculty, Poorsina St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2009-07-07, 1388/04/16

Ethics committee reference number

397

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Oocyte Methaphase 2

Timepoint

before and after embryo transfer

Method of measurement

diagnosed by Embryologist and with embryological criteria

2

Description

Embryo quality

Timepoint

2 days after embryo transfer

Method of measurement

diagnosed by Embryologist and with embryological criteria

3

Description

Oocyte Fertilization rate

Timepoint

first day after embryo transfer

Method of measurement

diagnosed by Embryologist and with embryological criteria

Secondary outcomes

1

Description

Take home baby

Timepoint

9 months after Embryo transfer

Method of measurement

Delivery

2

Description

Biochemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

B-hcg

3

Description

Clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

sac observed in vaginal Sonography

4

Description

Miscarriage

Timepoint

<12 weeks after embryo transfer

Method of measurement

vaginal sonography

Intervention groups

1

Description

Intervention group : Accuponcture based on Traditional Chinese Medicine, 5 sessins of thirty minutes.

Category

Treatment - Other

2

Description

Control group: (Placebo) the same needles are used in 5 sessions of thirty minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaya Mehr Clinic

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Faculty, Tehran University of Medical Sciences

Full name of responsible person

Maryam Khorami

Street address

Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Medical Faculty, Tehran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Vali-e-asr Reproductive Health Research Center

Full name of responsible person

Rashidi Batool

Position

Associate Proffesor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Vali-e-asr Reproductive Health Research Center

Full name of responsible person

Haghollahi Fedyeh

Position

Msc

Other areas of specialty/work

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fedyeh_hagh@yahoo.com

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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