

# 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)

###### Phone

+98 21 6693 9320

###### Email address

bhrashidi@tums.ac.ir

##### 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**

##### **Street address**

Tehran University of Medical Sciences, Valieasr Hospital and Imam khomeini Hospital

##### **City**

Tehran

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##### **Phone**

+98 21 6693 9320

##### **Fax**

##### **Email**

bhrashidi@tums.ac.ir

##### **Web page address**

### **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**

##### **Street address**

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Tehran

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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*