

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The effect of acupuncture on in vitro fertilization/ intracytoplasmic sperm injection embryo transfer outcomes in patients with poor ovarian response diagnosis: A randomized controlled trial

#### Protocol summary

##### Study aim

To evaluate the effect of acupuncture during ovarian stimulation on IVF/ICSI outcomes in patients with poor ovarian response diagnosis

##### Design

Two arm parallel group randomised trial (not- blinded) postoperative care and outcome assessment

##### Settings and conduct

This study is conducted at Infertility Department of Reproductive Bio-medicine Research Center, Royan institute, Tehran, Iran.

##### Participants/Inclusion and exclusion criteria

The diagnosis of poor ovarian response (POR), according to POSSEIDON group criteria (Group 3): Young patients (<35 years) with poor ovarian reserve pre-stimulation parameters [antral follicle count (AFC) <5, anti-Müllerian hormone (AMH) <1.2 ng/mL].

##### Intervention groups

Acupuncture twice a week during the preceding cycle and the ovarian stimulation by "gonadotropin releasing hormone (GnRH) agonist stopped protocol. All patients will receive acupuncture by the same physician (Dr.Salimi). In experimental groups, acupuncture will be applied for 30 minutes in each session and will be started from the month prior to onset of ovarian stimulation (two sessions of a weekly), and during the ovarian stimulation cycle (two sessions of a weekly), totally 14 acupuncture sessions will be carried out. Acupuncture will be performed using sterile needle on specific points (CV 3 (Zhongji), CV 4 (Guanyuan), ST 25 (Tianshu), ST 28 (Shuidao), ST 29 (Guilai), and LR 3 (Taichong), BL 23 (Shenshu), BL 32 (Ciliao), GV 20 (Baihui), GV 24 (Shenting), GB 13 (Benshen), ST 36 (Zusanli), SP 6 (Sanyinjiao), SP 8, SP 10 and KI 3 (Taixi)). The needles were inserted to a depth of 15-30 mm, depending on the region of the body.

##### Main outcome variables

Primary consequences: the total number of retrieved and metaphase II (MII) oocytes and quality of the obtained embryos. Secondary outcomes : implantation and clinical pregnancy rates.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080831001141N26**

Registration date: **2019-03-27, 1398/01/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-27, 1398/01/07**

Update count: **0**

##### Registration date

2019-03-27, 1398/01/07

##### Registrant information

##### Name

Kiandokht Kiani

##### Name of organization / entity

Royan Institute

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2230 7960

##### Email address

kiandokht.kiani@royaninstitute.org

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2020-04-20, 1399/02/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of acupuncture on in vitro fertilization/ intracytoplasmic sperm injection embryo transfer outcomes in patients with poor ovarian response diagnosis: A randomized controlled trial

**Public title**

The effect of acupuncture for treatment of patients with poor ovarian response

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of Poor ovarian response (POR), according to POSSEIDON group criteria (Group 3): Young patients (<35 years) with poor ovarian reserve pre-stimulation parameters (antral follicle count (AFC) <5, anti-Müllerian hormone <1.2 ng/mL).

**Exclusion criteria:**

Premature ovarian failure diagnosis Endometriosis grade III or IV Any contraindications to ovarian stimulation treatment Uterine infertility factor Previous history of ovarian surgery

**Age**

To 35 years old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method was designed by epidemiologist using STATA software version 13 and the number of blocks considered is 6. The random allocation list for patients was solely available to the epidemiologist. In order to hide the random allocation process, a total of 60 envelopes were prepared, and only the methodologist has been aware of table of random numbers. When the doctor declared the patient's eligibility, the methodologist provided the doctor with the envelope. The group was selected based on the type of group mentioned in the envelope.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Royan infertility institute

**Street address**

Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

16656-59911

**Approval date**

2016-01-12, 1394/10/22

**Ethics committee reference number**

IR.ACECR.ROYAN.REC.1394.52

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

Poor ovarian response during controlled ovary stimulation in in vitro fertilization cycles

**ICD-10 code**

N98.2

**ICD-10 code description**

Complications of attempted introduction of fertilized ovum following in vitro fertilization

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

Total number of retrieved oocytes

**Timepoint**

34-36 hours after final oocyte triggering

**Method of measurement**

The number of oocytes counted by an embryologist

**2****Description**

Total number of MII oocytes

**Timepoint**

34-36 hours final oocyte triggering

**Method of measurement**

The number of metaphase II oocytes counted by an embryologist

**Secondary outcomes**

## 1

### Description

Implantation rate

### Timepoint

4-6 weeks after embryo transfer

### Method of measurement

By dividing the number of gestational sacs by the number of embryos transferred

## 2

### Description

Clinical pregnancy rate

### Timepoint

5-7 weeks after embryo transfer

### Method of measurement

By detection of fetal heart beat in vaginal sonography 5 - 7 weeks after transfer

## Intervention groups

### 1

#### Description

Intervention group: acupuncture is done twice a week during the preceding cycle and the ovarian stimulation is performed by "gonadotropin releasing hormone (GnRH) agonist stopped protocol. All patients will receive acupuncture by the same physician (Dr.Salimi). In experimental groups, acupuncture will be applied for 30 minutes in each session and will be started from the month prior to onset of ovarian stimulation (two sessions of a weekly), and during the ovarian stimulation cycle (two sessions of a weekly), totally 7 acupuncture sessions will be carried out. Acupuncture will be performed using sterile needle on specific points (CV 3 (Zhongji), CV 4 (Guanyuan), ST 25 (Tianshu), ST 28 (Shuidao), ST 29 (Guilai), and LR 3 (Taichong), BL 23 (Shenshu), BL 32 (Ciliao), GV 20 (Baihui), GV 24 (Shenting), GB 13 (Benshen), ST 36 (Zusanli), SP 6 (Sanyinjiao), SP 8, SP 10 and KI 3 (Taixi)). The needles were inserted to a depth of 15-30 mm, depending on the region of the body.

#### Category

Treatment - Other

### 2

#### Description

Control group: ovarian stimulation was performed by "GnRH agonist stopped protocol" without any other intervention.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Royan Institute

#### Full name of responsible person

Mahnaz Ashrafi

#### Street address

No.12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

16656-59911.

#### Phone

+98 21 2356 2640

#### Email

mashrafi@royaninstitute.org

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Royan Institute

##### Full name of responsible person

Mahnaz Ashrafi

##### Street address

Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

16656-59911.

##### Phone

+98 21 2356 2640

##### Email

mashrafi@royaninstitute.org

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Royan Institute

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Royan Institute

**Full name of responsible person**

Arezoo Arabipoor

**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Number 12, East Hafez Avenue, Bani Hashem Street,  
Resalat Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

16656-59911

**Phone**

+98 21 2356 2642

**Email**

arezoo.arabipoor@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Royan Institute

**Full name of responsible person**

Tayebeh Salimi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Number 12, East Hafez Avenue, Bani Hashem Street,  
Resalat Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

16656-59911.

**Phone**

+98 21 2356 2218

**Email**

tayebehsalimi@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Royan Institute

**Full name of responsible person**

Azar Yahyaei

**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Number 12, East Hafez Avenue, Bani Hashem Street,  
Resalat Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

16656-59911

**Phone**

+98 21 2356 2647

**Email**

azar.yahyaei@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Specific participant data sets are to be shared (e.g., all collected deidentified IPD, IPD collected for the primary outcome measure only, etc).

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

The study data only available for people working in academic institutions.

**Under which criteria data/document could be used**

Data will be sent to the study in the case of correspondence between the research centers and the written request, if registered and referenced

**From where data/document is obtainable**

Applicants must contact the scientific responsible through a contact number or email.

**What processes are involved for a request to access data/document**

After completing the correspondence with the academic officer and ensuring that the study data will be used by considering the right of authorship and reference, data will be sent within one to two weeks.

**Comments**