Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 2230 7960

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