

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigation of intrauterine saline infusion at day 3 to 5 of ovarian stimulation on the clinical outcome of Intracytoplasmic sperm injection-embryo transfer cycles in patients with repeated implantation failure.

#### Protocol summary

##### Summary

Objective: to investigate the effect of normal saline infusion into the uterine cavity on clinical pregnancy and implantation and abortion rate in ovarian stimulation cycles of intracytoplasmic sperm injection cycles - embryo transfer in patients with recurrent implantation failure. Design: Randomized Clinical Trial. Setting and conduct and participants including major eligibility: in patients aged 20-45 years who have failed two or more intracytoplasmic sperm injection-embryo transfer cycles despite transfer of good quality embryos and Now undergoing intracytoplasmic sperm injection -embryo transfer or freeze embryo transfer cycles, Have normal hysterosalpingography or hysteroscopy are included in study. Intervention: during the fresh intracytoplasmic sperm injection-embryo transfer cycles or next freeze embryo transfer cycle, Or cycles continue without any interventions or on stimulation days 3 to 5 in fresh cycles and on day 3 to 5 from starting of oral estradiol in freeze embryo transfer cycles, randomly we are injecting 20 CC of normal saline by intrauterine insemination catheter under ultrasonography guide in to the uterine cavity and then suctioning it and then in both groups, in fresh intracytoplasmic sperm injection-embryo transfer cycles with gonadotropins injection and if necessary Antagonist will be continue and when 2 or 3 follicles reach to a diameter of 17 mm, 10,000 units of human chorionic gonadotropin ampoules will be injected and oocyte retrieval will be performed 34 to 36 hours later and in freeze embryo transfer group continuing estradiol and when endometrial thickness are receiving to 7 millimeter, then starting suppository vaginal progesterone 400 milligram twice daily and three days after oocyte injection in fresh cycles and on day 4 of progesterone administration, 2 to 3 embryos that have 6-8 cells are transferring through the vagina into the patients uterus. Main outcome measure (variables

criteria): 15 days after embryo transfer, chemical pregnancy will be confirmed or rule out by positive BHCG test and 3-4 weeks later; the clinical pregnancy with vaginal ultrasound and then we will compare the pregnancy and the implantation and the miscarriage results between the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120219426N3**

Registration date: **2014-12-07, 1393/09/16**

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

Last update:

Update count: **0**

##### Registration date

2014-12-07, 1393/09/16

##### Registrant information

##### Name

Saghar Salehpour

##### Name of organization / entity

Shahid Behshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 2558

##### Email address

saghar.salehpour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Science

##### Expected recruitment start date

2014-04-21, 1393/02/01  
**Expected recruitment end date**  
2015-01-20, 1393/10/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Investigation of intrauterine saline infusion at day 3 to 5 of ovarian stimulation on the clinical outcome of Intracytoplasmic sperm injection- embryo transfer cycles in patients with repeated implantation failure.

**Public title**  
Effects of normal saline infusion on pregnancy rate

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: women aged 20-45 years old, undergoing ICSI-ET or freeze embryo transfer; normal hysterosalpingography or hysteroscopy; at least 2 previous failed intracytoplasmic sperm injection-embryo transfer cycles despite transfer of good quality embryos. Exclusion criteria: abnormal uterine cavity in hysterosalpingography or hysteroscopy; poor responders in previous hormonal stimulation cycles (less than 4 follicles with a size greater than 14 mm on the day of Human chorionic gonadotropin injection).

**Age**  
From **20 years** old to **45 years** old

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**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**  
Infertility & Reproductive Health Research Center  
Ethics committee of Shahid Beheshti University of  
**Street address**  
3rd floor, Taleghani Hospital, Velenjak, Shahid  
Chamran highway, Tehran  
**City**  
Tehran  
**Postal code**  
1985711151

**Approval date**  
2014-04-09, 1393/01/20  
**Ethics committee reference number**  
93/349

## Health conditions studied

**1**  
**Description of health condition studied**  
Noninflammatory disorders of female genital tract  
**ICD-10 code**  
N98  
**ICD-10 code description**  
Complications associated with artificial fertilization

## Primary outcomes

**1**  
**Description**  
Clinical pregnancy  
**Timepoint**  
Four weeks after embryo transfer  
**Method of measurement**  
Vaginal ultrasonography

## Secondary outcomes

**1**  
**Description**  
Chemical pregnancy  
**Timepoint**  
Two weeks after embryo transfer  
**Method of measurement**  
B HCG kit

**2**  
**Description**  
Ongoing pregnancy  
**Timepoint**  
Ten weeks after embryo transfer  
**Method of measurement**  
Transabdominal ultrasonography

**3**  
**Description**  
Miscarriage rate  
**Timepoint**

22 weeks after embryo transfer  
**Method of measurement**  
History, Ultrasonography

## Intervention groups

### 1

#### Description

Intervention: on days 3 to 5 of the stimulation cycles randomly injecting 20 mL of saline by IUI catheters in to the intrauterine cavity with ultrasound guidance and then suctioned out.

#### Category

Treatment - Other

### 2

#### Description

Control: Stimulation cycles continued without any intervention

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Infertility & Reproductive Health Research Center  
Shahid Beheshti University of Medical Science

##### Full name of responsible person

Zahra Sadeghzadeh

##### Street address

Taleghani hospital , Velenjak, Shahid Chamran highway, Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Science

##### Full name of responsible person

Zahra Sadeghzadeh

##### Street address

IVF ward, Taleghani hospital, Velenjak , Shahid Chamran highway, Tehran

##### City

Tehran

#### Grant name

-

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Science

#### 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

##### Name of organization / entity

Infertility & Reproductive Health Research Center  
Shahid Beheshti University of Medical Science

##### Full name of responsible person

Saghar Salehpour

##### Position

Associate professor

##### Other areas of specialty/work

##### Street address

IVF ward, Taleghani Hospital, Velenjak, Shahid Chamran highway, Tehran

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Infertility & Reproductive Health Research Centre -  
Shahid Beheshti of Medical Science

##### Full name of responsible person

Marzieh Zamaniyan

##### Position

Gynecologist

##### Other areas of specialty/work

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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Shahid Beheshti of Medical Science

**Full name of responsible person**

Saghar Salehpour

**Position**

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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*