

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

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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

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IVF ward, Taleghani hospital, Velenjak , Shahid
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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

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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