

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The sequential embryo transfer in the third and fifth day compared to single embryo transfer in the fifth day in IVF cycle

Protocol summary

Study aim

evaluation of the twice embryo transfer on day 3 or day 5 (blastocyst) compared with the embryo transfer on the fifth day in women with a history of at least three failed IVF

Design

The third phase of this randomized clinical trial, two groups of 120 subjects were assigned to two parallel groups of intervention (embryo transfer on days 3 and 5) and control (embryo transfer on the fifth day (blastocyst)).

Settings and conduct

Published data on sequential transfer is limited. Also, the effectiveness of this procedure is still a matter of debate. So, this study was aimed to evaluate the sequential embryo transfer on day 3 or day 5-blastocyst compared to single transfer on day 5 (blastocyst) in women with a history of at least three IVF failures referred to Imam Khomeini Infertility clinic. After the ovarian stimulation, oocyte retrieval, inoculation of sperm into the oocyte and embryo formation, The included patients were randomly divided into two groups. In the intervention group, 1 number of the embryo was transferred on the third day and two embryos on the fifth day (blastocyst) and in the control group, two blastocysts were transferred to the uterus.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women with less than 40 years of age with more than three times IVF failure, normal karyotype, immunological status and thrombophilia, lack of anomalies in the endometrium. Exclusion criteria: patients with poor or ovarian hyperstimulation syndrome, underlying medical conditions.

Intervention groups

Intervention group: In the number of 60 eligible patients after ovulation stimulation and embryo formation, the embryos were transferred to the third and fifth days on two occasions Control group: Two embryos were transferred to fifth days on one occasion.

Main outcome variables

Chemical pregnancy : Clinical Pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141217020351N10**

Registration date: **2018-05-13, 1397/02/23**

Registration timing: **retrospective**

Last update: **2018-05-13, 1397/02/23**

Update count: **0**

Registration date

2018-05-13, 1397/02/23

Registrant information

Name

Ensieh Shahrogh Tehraninejad

Name of organization / entity

Tehran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-04-09, 1394/01/20

Expected recruitment end date

2016-04-08, 1395/01/20

Actual recruitment start date

2015-04-09, 1394/01/20

Actual recruitment end date

2016-04-08, 1395/01/20

Trial completion date
empty

Scientific title
The sequential embryo transfer in the third and fifth day compared to single embryo transfer in the fifth day in IVF cycle

Public title
The sequential embryo transfer compared to single embryo transfer in one cycle

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age \leq 40 years normal karyotype normal screening of immunological and thrombolytic condition the absence of endometrial abnormalities by hysteroscopy availability of \geq 5 embryos
Exclusion criteria:
potential poor responders Ovarian hyper stimulation response presence of medical diseases

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **130**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
they were allocated to one of two groups via simple random sampling, using a random Pocket (intervention or Control) by the same coordinator. Patients were allocated to either sequential transfer (day 3 and day 5) or conventional transfer (day 5) protocols.

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 Tehran University of Medical

Sciences

Street address
No.6,Ghods Ave,Keshavarz Blvd,Deputy of Research of Tehran University of Medical Sciences

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Tehran

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Postal code
14194

Approval date
2017-07-11, 1396/04/20

Ethics committee reference number
IR.TUMS.IKHC.REC.1396.3849

Health conditions studied

1

Description of health condition studied

Infertility, Repeated implantation failure, Embryo transfer, Blastocyst

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

Two weeks after the stopping the menstruation

Method of measurement

Blood sample for B-HCG

2

Description

Clinical Pregnancy

Timepoint

Six weeks after seeing the embryo sac in ultrasound

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Abortion

Timepoint

After positive pregnancy test

Method of measurement

Blood sample of B-HCG

2

Description

Ectopic pregnancy

Timepoint

After the positive of pregnancy test

Method of measurement

Sonography

Intervention groups**1****Description**

Intervention group: patients were randomized to one of the 2 groups of Intervention and control .After ovulation induction, When 3leading follicles reached more than 17 mm diameter means, oocyte retrieval was performed 36 hours later under the unconscious sedation. The retrieved oocytes were incubated in a mini-incubator with the triple gas mixture for 3h in a fertilization medium and then ICSI was done. Injected oocytes were transferred to a culture dish with cleavage medium (Sydney IVF cleavage medium, cook). Fertilization was assessed 16-18 h after ICSI and then observed for cleavage on day 3. Once post-fertilization check confirmed availability of ≥ 5 embryos, . In the third day after injection, embryo quality was evaluated, and 1 good-quality embryos were transferred (Cleavage in fresh cycles). Also, embryos were transferred to Blastocyst medium (Sydney IVF blastocyst medium) for 48 h. Then, on the fifth day, two embryos (Blastocyst) were transferred to the uterus.

Category

Treatment - Surgery

2**Description**

Control group: After ovulation induction, When 3leading follicles reached more than 17 mm diameter means, oocyte retrieval was performed 36 hours later under the unconscious sedation. The retrieved oocytes were incubated in a mini-incubator with the triple gas mixture for 3h in a fertilization medium and then ICSI was done. Injected oocytes were transferred to a culture dish with cleavage medium (Sydney IVF cleavage medium, cook). Fertilization was assessed 16-18 h after ICSI and then observed for cleavage on day 3. Once post-fertilization check confirmed availability of ≥ 5 embryos, In the control group, on the fifth day, two embryos (Blastocyst) were transferred to the uterus.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali asr Infertility Clinic

Full name of responsible person

Fatemeh Bakhtiari Ghaleh

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Valiasr Infertility Clinic ,Imamkhomeini

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

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

Tehran University of Medical Sciences

Full name of responsible person

Ensieh Shahrokh Tehraninejad

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Infertility

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

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Position

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Other areas of specialty/work

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

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Researcher

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Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Maintaining privacy in patient data

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available