

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial comparing pregnancy rate in transfer of blastocyst vs cleavage stage in assisted reproductive technology

Protocol summary

Study aim

Comparing pregnancy rate in transfer of blastocyst vs cleavage stage in assisted reproductive technology

Design

Block randomization . double blind, 220 participant

Settings and conduct

Three ovarian stimulation protocols(long protocol , microdose and antagonist protocol) were used to prepare patients for ivf depending on their age and diagnosis. Final oocyte maturation was induced by administration of 10 000 IU hCG when at least three follicles with a diameter of 17 mm were observed during pelvic ultrasound. Oocyte retrieval was performed by vaginal ultrasound-guided puncture 36 h after hCG administration. . Oocytes incubated in IVF medium at 37 °C with 7.3%CO₂ and 5 % O₂ in air with saturated humidity. Then surrounding cumulus oophorus and corona radiata cells removed for intracytoplasmic sperm injection (ICSI). Finally Oocytes were fertilized by either insemination (IVF) or ICSI. embryos were cultured in sequential media . The women will be randomly divided into two groups A fresh transfer was performed either on Day 3 or on day 5 after.The luteal phase was supported by vaginal progesterone 600 mg daily.

Participants/Inclusion and exclusion criteria

Inclusion criteria:uterine with normal cavity; Normal respond er to ovarian stimulation;there are at least 5 fresh embryos and sufficient thickness of endometrium in day 12 cycles Exclusion criteria: lack of embryo with good quality ;endocrine disorder(Hypothyroidism ,diabetes); poor respond er(less and equal 3 oocyte) ;Excessive responder to ovarian stimulation (more than 20oocyte);freeze all of all embryos; previous surgery of uterine ;recurrent abortion ; sever male factor and refusal to cooperation in the study

Intervention groups

In one group, a three-day embryo is transferred and in another group five-day fetus is transferred

Main outcome variables

Clinical pregnancy rate ,chemical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041503N1**

Registration date: **2019-02-16, 1397/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-16, 1397/11/27**

Update count: **0**

Registration date

2019-02-16, 1397/11/27

Registrant information

Name

Malihe Mahmoudinia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3882 9878

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Clinical trial comparing pregnancy rate in transfer of blastocyst vs cleavage stage in assisted reproductive technology
Public title	Clinical pregnancy rate in transfer of fresh embryo , 5 days vs 3 days
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Uterine with normal cavity Normal res ponder to ovarian stimulation There are at least 5 fresh embryo Sufficient thickness of endometrium in day 12 cycles Exclusion criteria: lack of embryo with good quality Endocrine disorder(Hypothyroidism ,diabetes) Poor respond er(less and equal 3 oocyte) Excessive responder to ovarian stimulation (more than 20oocyte) Freeze all of all embryos Refusal to cooperation in the study previous surgery of uterine Recurrent abortion Sever male factor
Age	From 20 years old to 40 years old
Gender	Female
Phase	N/A
Groups that have been masked	• Participant • Investigator • Outcome assessor
Sample size	Target sample size: 220
Randomization (investigator's opinion)	Randomized
Randomization description	The random list is using the PASS software.The type of randomization is simple . The analyst and doctor will be unaware of the intervention and control groups.
Blinding (investigator's opinion)	Triple blinded
Blinding description	The researcher does not know how to randomize .The Embryologist chooses patients according to random numbers in each group.Patient and evaluator of the results are not known from the assigned group
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Mashhad university of Medical sciences Ethics committee
Street address	Mashhad University of Medical Sciences, Mashhad University of Medical Sciences,University Avenue, Mashhad
City	Mashhad
Province	Razavi Khorasan
Postal code	9138813944
Approval date	2018-07-25, 1397/05/03
Ethics committee reference number	617.IR.MUMS.MEDICAL.REC.1397
Health conditions studied	
<u>1</u>	
Description of health condition studied	Transfer of fresh embryo in assisted reproductive technology
ICD-10 code	N98.3
ICD-10 code description	Complications of attempted introduction of embryo in embryo transfer
Primary outcomes	
<u>1</u>	
Description	Clinical pregnancy rate
Timepoint	6 weeks after embryo transfer
Method of measurement	sonography
<u>2</u>	
Description	Chemical pregnancy rate
Timepoint	2weeks after embryo transfer
Method of measurement	βHCG test
Secondary outcomes	
<u>1</u>	
Description	

Ongoing pregnancy
Timepoint
Continued pregnancy up to 12 weeks
Method of measurement
Trans vaginal Sonography

Intervention groups

1

Description

Intervention group: Three ovarian stimulation protocols (long protocol, microdose and antagonist protocol) were used to prepare patients for ivf depending on their age and diagnosis. Final oocyte maturation was induced by administration of 10 000 IU hCG when at least three follicles with a diameter of 17 mm were observed during pelvic ultrasound. Oocyte retrieval was performed by vaginal ultrasound-guided puncture 36 h after hCG administration. Oocytes incubated in IVF medium at 37 °C with 6 %CO₂ and 5 % O₂ in air with saturated humidity. Finally Oocytes were fertilized by either insemination (IVF) or ICSI. Embryos were cultured in sequential media. The women will be randomly divided into two groups A fresh transfer was performed either on Day 3 or on day 5 after pick up. The luteal phase was supported by utrogestan Vaginal 600 mg daily.

Category

Treatment - Other

2

Description

Control group: Three ovarian stimulation protocols (long protocol, microdose and antagonist protocol) were used to prepare patients for ivf depending on their age and diagnosis. Final oocyte maturation was induced by administration of 10 000 IU hCG when at least three follicles with a diameter of 17 mm were observed during pelvic ultrasound. Oocyte retrieval was performed by vaginal ultrasound-guided puncture 36 h after hCG administration. Oocytes incubated in IVF medium at 37 °C with 6%CO₂ and 5 % O₂ in air with saturated humidity. Then surrounding cumulus oophorus and corona radiata cells removed for intracytoplasmic sperm injection (ICSI). Finally Oocytes were fertilized by either insemination (IVF) or ICSI. embryos were cultured in sequential media. The women will be randomly divided into two groups. A fresh transfer was performed either on Day 3 or on day 5 after pick up. The luteal phase was supported by utrogestan vaginal (utrogestan, Besins, Brussels, Belgium) 600 mg daily.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Milad Infertility Center

Full name of responsible person

Malihi Mahmoudinia

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Milad Infertility center, Mashhad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen, Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Mahmoudinia

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Nayyereh khadem

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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

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

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