Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 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 , microdoze 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)

Phone
+98 51 3882 9878

Email address
mahmoudiniam@mums.ac.ir

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

1

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

1

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

1

Description
Clinical pregnancy rate

Timepoint
6 weeks after embryo transfer

Method of measurement
sonography

2

Description
Chemical pregnancy rate

Timepoint
2weeks after embryo transfer

Method of measurement
βHCG test

Secondary outcomes

1

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 , microdoze 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 , microdoze 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

Malihh Mahmoudinia

Street address

Milad Infertility center, Mashhad, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9135913556

Phone

+98 51 3853 4021

Email

mahmoudiniam941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen,Tafaghodi

Street address

Vice Chancellor Of Research,Mashhad University of Medical Sciences ,Mashhad University of Medical Sciences,University Avenue ,Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

Tafaghodim@mums.ac.ir

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
Street address
Milad Fertility Clinic, East Razi Street, Dah e Day Square,
City
Mashhad
Province
Razavi Khorasan
Postal code
9178631973
Phone
+98 51 3853 4021
Email
MahmoudiniaM@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Nayyereh khadem
Position
professor of gynecology group
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Emam Reza Hospital, Ebne Sina Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9178631973
Phone
+98 51 3801 2607
Email
khademn@mums.ac.ir

Person responsible for updating data

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
Street address
Milad Fertility Clinic, East Razi Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9135913556
Phone
+98 51 3853 4031
Email
MahmoudiniaM@mums.ac.ir

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