Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of intrauterine injection of chorionic gonadotropin hormon before transfer of fresh and freezee mbryo on outcome of IVF and ICSI

Protocol summary

Study aim
Effect of intrauterine injection of chorionic gonadotropin hormon before transfer of fresh and freezee mbryo on outcome of IVF and ICSI

Design
Random Assignment to Intervention and Control Groups by Randomized Double-Blind Randomized Blocking Sample Size 416 .

Settings and conduct
This is a double blind randomized clinical trial (doctor and patient unaware). The method of assigning patients to treatment groups is randomly assigned to treatment groups and individuals will be assigned to groups. Patients are divided into two groups of embryo transfer. The new transition group uses three protocols for IVF readiness based on age and patient diagnosis.Endometrial preparation freeze embryo transfer cycles are performed with one of the three protocols of hormone therapy, natural or ovarian stimulation depending on each patient's condition. Preparation of hcg for intrauterine injection before transfer to control group is done by adding HCG500IU to .40 µl of media.In the control group, the same volume of media is injected alone in the intervention group. After 4 minutes, transplantation of one or two embryo is performed by abdominal sonography . 600 mg of vaginal urethrogestan is given daily for luteal phase support.

Participants/Inclusion and exclusion criteria
Infertile women (18-42 years old) with a history of infertility due to unspecified or male infertility who are referred to IVF-ICSI for treatment and undergo IVF-ICSI cycle -no severe oligospermia - no uterine anomaly or no uterine surgery Exclusion criteria: patient's unwillingness to continue the cycle - lack of endometrial thickness inappropriate for transfer - lack of quality A or B embryos for transfer

Intervention groups
Women undergoing embryo transfer cycle receive intrauterine injection of HCG

Main outcome variables
Clinical pregnancy rate ,chemical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181030041503N2**
Registration date: **2020-03-05, 1398/12/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-05, 1398/12/15**
Update count: **0**

Registration date
2020-03-05, 1398/12/15

Registrant information

Name
Malihe Mahmoudinia
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-04, 1398/11/15

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of intrauterine injection of chorionic gonadotropin hormon before transfer of fresh and freezee mbryo on outcome of IVF and ICSI

Public title
Effect of intrauterine injection of chorionic gonadotropin hormon before transfer of fresh and freezee mbryo on outcome of IVF

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-42 years A history of infertility for unknown reasons or male factor Indication for IVF

Exclusion criteria:
SEVER OLIGOSPERMIA Uterine abnormality Uterine Surgery History

Age
From **18 years** old to **42 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **416**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation blocks will be used to assign treatment to the two groups, in which the new transfer group will specify the control group with the letter a and the intervention group with the letter b, each block size 4, the number of blocks 26 and the number of permutations. There are 4 possible cases. Then random number table] or using simulation software in runif (26, min = 1, max = 4) [R, select 26 random numbers and fill 26 blocks of states. The same goes for the Freeze groupgroups

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patient is unaware of treatment - doctor who performing transfer not aware of fluid that injected into uterus .Fluid delivered to physician based on randomized list - Analysistt not aware of treatment

Placebo
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
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

Approval date
2019-12-05, 1398/09/14

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.708

Health conditions studied

1

Description of health condition studied
Feresh and freeze transfer after intrautrine HCG injection

ICD-10 code
N98.3

ICD-10 code description
Complications of attempted introduction of embryo in embryo transfer

Primary outcomes

1

Description
Chemical pregnancy rate

Timepoint
2weeks after embryo transfer

Method of measurement
βHCG test

2

Description
Clinical pregnancy rate

Timepoint
6 week after embryo transfer

Method of measurement
sonography

Secondary outcomes

1

Description

Ongoing pregnancy

Timepoint

Continued pregnancy up to 12

Method of measurement

Trans vaginal Sonography

Intervention groups

1

Description

Intervention group:Intervention group: In the fresh transfer group based on age and patient diagnosis, three protocols for IVF preparation are used. In the long-acting GnRH agonist method, 500 micrograms of subcutaneous GnRH analogue (buserelin, supernatant) is started on day 21 of the preceding cycle and is reduced to 200 micrograms from the second day of the analogue dose cycle. In the micro-dose method, the supernatant begins the second day of the cycle. Starts. In the long-term GnRH agonist method after providing ovarian suppression according to the ultrasound view, and in other protocols, from the second or third day of the recombinant gonadotropin cycle (puregon, organon, Netherland, gonl, Merck-, Europe, ltd). , uk (serono starts)The starting dose of gonadotropins is determined by the patient's age, previous cycle, ovarian reserve. 5 days after stimulation with gonadotropins, the first ovarian monitoring is performed by ultrasound and dose adjusted as needed. HMG is added when Lh is required. When at least three follicles reach 17 mm, 10,000 units of HCG are prescribed. 36 hours after HCG administration, ovulation is performed under general anesthesia. The oocytes obtained were maintained in Cleave medium (Origio-Denmark) at 37 ° C with 26% Co and 5% o 2 and then the cumulus cells were removed around the oocyte, Finally, intracytoplasmic sperm injection is performed. Embryos are cultured in successive media. The embryos are examined daily for quality. Each blast or clavage of one or two embryos of high quality A or B is frozen to transfer selection and the other embryos are frozen.in freeze transfer group Preparation Of endometrium is performed with one of the three ;hormone therapy protocols, natural or ovarian stimulation depending on each patient's condition. Preparation of hcg for intrauterine injection prior to transfer IN BOTH intervention group is performed by adding 500 IuHCG with 40 µl of media (origio.Denmark).and Before transfER injected to uterine., after 4 minutes of one or two embryo transfer with one or using a Cook (Australia) catheter and abdominal sonography. 600 mg urethrgestan for luteal phase support (utrogestan, Besins, Brussels, Belgium) is given daily vaginally. BHCG is measured 14 days after transfer. Chemical pregnancy The appearance of BHCG in the blood is 2 weeks after clinical transfusions at 6 weeks of gestation . ongoing pregnancy is continued for up to 12 weeks.

Category

Treatment - Other

2

Description

Intervention group:Intervention group: In the fresh transfer group based on age and patient diagnosis, three protocols for IVF preparation are used. In the long-acting GnRH agonist method, 500 micrograms of subcutaneous GnRH analogue (buserelin, supernatant) is started on day 21 of the preceding cycle and is reduced to 200 micrograms from the second day of the analogue dose cycle. In the micro-dose method, the supernatant begins the second day of the cycle. Starts. In the long-term GnRH agonist method after providing ovarian suppression according to the ultrasound view, and in other protocols, from the second or third day of the recombinant gonadotropin cycle (puregon, organon, Netherland, gonl, Merck-, Europe, ltd). , uk (serono starts)The starting dose of gonadotropins is determined by the patient's age, previous cycle, ovarian reserve. 5 days after stimulation with gonadotropins, the first ovarian monitoring is performed by ultrasound and dose adjusted as needed. HMG is added when Lh is required. When at least three follicles reach 17 mm, 10,000 units of HCG are prescribed. 36 hours after HCG administration, ovulation is performed under general anesthesia. The oocytes obtained were maintained in Cleave medium (Origio-Denmark) at 37 ° C with 26% Co and 5% o 2 and then the cumulus cells were removed around the oocyte, Finally, intracytoplasmic sperm injection is performed. Embryos are cultured in successive media. The embryos are examined daily for quality. Each blast or clavage of one or two embryos of high quality A or B is frozen to transfer selection and the other embryos are frozen.in freeze transfer group Preparation Of endometrium is performed with one of the three ;hormone therapy protocols, natural or ovarian stimulation depending on each patient's condition. Preparation of hcg for intrauterine injection prior to transfer IN BOTH intervention group is performed by adding 40 µl normalsalin as plasebo Before transfER injected to uterine., after 4 minutes of one or two embryo transfer with one or using a Cook (Australia) catheter and abdominal sonography. 600 mg urethrgestan for luteal phase support (utrogestan, Besins, Brussels, Belgium) is given daily vaginally. BHCG is measured 14 days after transfer. Chemical pregnancy The appearance of BHCG in the blood is 2 weeks after clinical transfusions at 6 weeks of gestation . ongoing pregnancy is continued for up to 12 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility center

Full name of responsible person

Malihh Mahmoudinia

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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for updating data

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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