Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the expression of genes involved in the process of apoptosis in cellulose cells in four groups of patients under the cycle of ovulation stimulation with antagonist or agonist GNRH with HP-FSH or FSH recombinant.

Protocol summary

Study aim
Examines the gene expression associated with progression and development and the quality of the resulting embryos in common methods in the induction of ovulation.

Design
Eighty eligible infertile patients underwent controlled ovarian stimulation using agonists and antagonists (in both recombinant and HP groups) will be placed in phase 2-3 non-random clinical trials.

Settings and conduct
Eligible infertile patients in Vali Asr Infertility Clinic of Imam Khomeini Hospital with the aim of; Investigation ovarian gene expression in four treatment groups (non-random) will be studied. As mentioned in the four treatment groups, the egg pick up is performed 36 hours after the last administration of therapy. Then cumulus cells of oocytes are isolated by adding a drop of the enzyme hyaluronidase and In oocyte, without cumulus cells, the expression of genes is read by PCR in all four treatment groups.

Participants/Inclusion and exclusion criteria
Infertile women 20-30 years old will include the study with proper ovarian response and the absence of unknown infertility, azoospermia, and ovarian hyperstimulation syndrome.

Intervention groups
In this study, four groups of 20 infertile women (ovulation stimulation) will include in the study. The first group: Agonist GnRH and FSH (HP); Group 2:Agonist GnRH and FSH (recombinant),group 3: Antagonist GnRH and FSH (HP) and Group 4: Antagonist GnRH and FSH (recombinant). In all intervention groups; The eggs are aspirated from the follicular fluid and rinsed several times, then a drop of hyaluronidase is added to them and the cumulus is separated.Gene extracts from Cumulus, At this stage, the first RNA is extracted and then C DNA; It is synthesized and used; Gene expression evaluation is used using real-time PCR method.

Main outcome variables
Egg maturation; Fertilization success rate; The rate of fetal development are the main outcomes of the study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101115005181N16**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**
Update count: **0**

Registration date
2020-06-12, 1399/03/23

Registrant information

Name
Batool Rashidi

Name of organization / entity
Vali E Asr Reproductive Health Research Center

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-01, 1399/03/12
Expected recruitment end date
2020-11-02, 1399/08/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the expression of genes involved in the process of apoptosis in cellulose cells in four groups of patients under the cycle of ovulation stimulation with antagonist or agonist GNRH with HP-FSH or FSH recombinant.

Public title
Study of the expression of genes involved in the process of death in oocytes in four groups of patients undergoing ovulation stimulation cycle with four therapies.
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
The age of 20- 30 years old. Normal response to induction of ovulation.
Exclusion criteria:
unexplained infertility Cause Azoospermia Ovarian hyper stimulation Syndrome
Age
From **20 years** old to **30 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Not 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
Ethics committee of Tehran University of Medical Sciences
Street address
Sixth floor, Deputy of Research and Technology, Central University Organization, Quds Street, , Keshavarz Boulevard,
City
Tehran
Province
Tehran
Postal code
14197-33141
Approval date
2017-06-02, 1396/03/12
Ethics committee reference number
IR.TUMS.VCR.REC.1396.2309

Health conditions studied

1

Description of health condition studied
Female Infertility
ICD-10 code
N97.0
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Maturation of Oocyte
Timepoint
36 hours after the last administration of treatment
Method of measurement
Electronic Microscope

2

Description
Fertilization rate
Timepoint
24 hours after intra cytoplasmic sperm injection
Method of measurement
Electronic Microscope

3

Description
Rate of Embryo development
Timepoint
The third day of intra cytoplasmic sperm injection
Method of measurement
Electronic Microscope

4

Description
The evaluation of Gene expression of HAS-2, BAX, BCL-2, VCAN, ALCAM, R PTGS-2 in cumulus of oocyte

Timepoint
The day of pick up ovum
Method of measurement
Real time PCR

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: 20 infertile patients who were stimulated using the Gnrh agonist ampoule (Cinafact) of Cinagen Company, from the 21th day of previous cycle , 20 IU subcutaneous daily up to 36 hours before oocyte pick up and 225 units FSH (HP) of Cinagen company from the third day of menstrual cycle, are administrated for at least 10 days.
Category
Treatment - Drugs

2

Description
The second intervention group: 20 infertile patients who were stimulated using the Gnrh agonist ampoule (Cinafact) of Cinagen Company, from the 21th day of previous cycle , 20 IU subcutaneous daily up to 36 hours before oocyte pick up and 225 units FSH (Recombinant) of Cinagen company from the third day of menstrual cycle, are administrated for at least 10 days.
Category
Treatment - Drugs

3

Description
The third intervention group: 20 infertile patients who were stimulated using the Gnrh antagonist ampoule (cetrotide) of Merck Company, from the 6th day of induction ovulation, 0.25 IU subcutaneous daily up to 36 hours before oocyte pick up and 225 units FSH (HP) of Cinagen company from the third day of menstrual cycle, are administrated for at least 10 days.
Category
Treatment - Drugs

4

Description
The Fourth intervention group: 20 infertile patients who were stimulated using the GnRH antagonist ampoule (cetrotide) of Merck Company, from the 6th day of induction ovulation, 0.25 IU subcutaneous daily up to 36 hours before oocyte pick up and 225 units FSH (recombinant) of Cinagen company from the third day of the menstrual cycle, are administrated for at least 10 days. In all intervention groups of 1-4; The eggs are aspirated from the follicular fluid and rinsed several times, then a drop of hyaluronidase is added to them and the cumulus is separated.Gene extract from Cumulus, At this stage, first RNA is extracted and then C DNA; It is synthesized and used; Gene expression evaluation is used using real-time PCR method.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
IVF Labratoary in Vali- Asr Hospital
Full name of responsible person
Said Azizollahi
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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
Saeed Azizollahi
Position
Reproductive Biology Specialist
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
No - There is not a plan to make this available