

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

AgeFrom **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,

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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 (Cinactin) 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 (Cinactin) 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 Labratory in Vali- Asr Hospital

Full name of responsible person

Said Azizollahi

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

Tehran University of Medical Sciences

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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

Ph.D.

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