

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

A comparative study of the use of dydrogesterone and GnRH antagonists in InVitro Fertilization (IVF) cycles.

Protocol summary

Study aim

Evaluate the effect of using dydrogesterone and its comparison with Gonadotropin-releasing hormone (GnRH) on induction of ovulation in IVF patients.

Design

Parallel intervention study, type of randomized clinical trial, on 200 patients. Patients are randomly divided into two groups of Intervention and Control group by using the random numbers table.

Settings and conduct

A clinical trial study on 200 infertile women who are candidates for IVF in the Vali Asr Infertility Center of Tehran University of Medical Sciences. A random-simple-double-blind method using a random numbers table which the researcher selects to read the numbers from top to bottom and then considers the pair numbers for the intervention group and the individual numbers for the control group. Participants and researchers or evaluators are not aware of the allocation of the study group.

Participants/Inclusion and exclusion criteria

Infertility candidates for IVF, aged less than 40 years, AMH greater than 1.5 ng / ml; in the first or second cycles of VF; are the inclusion criteria and Cigarette smoking, having the uterine anomalies; uncontrolled thyroid or adrenal insufficiency; endometriosis grade 3 or more; couples' chromosomal abnormalities; underlying disorders leading to ovulation disorders are the exclusion criteria.

Intervention groups

Study group: On 2-3 days of menstrual cycle, oral progesterone or dydrogesterone (Duphaston 20 mg daily, oral) and hMG (225-150 units per day) are prescribed for 10 to 12 hours, then decapeptide 0.2 cc is given. Control group: On day 2-3 of the menstrual cycles, the hMG (225-150 injectable unit daily) and the antagonist Cetrotide (GnRH, 0.25 mg) are injected subcutaneously every 24 seconds, given for 10-12 days, and Decapeptide will then be administered at 0.2 cc.

Main outcome variables

Number of the mature oocytes, LH surge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181031041519N2**

Registration date: **2019-06-10, 1398/03/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-10, 1398/03/20**

Update count: **0**

Registration date

2019-06-10, 1398/03/20

Registrant information

Name

Seyyedeh Tahere Ghazimirsaeed

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the use of dydrogesterone and GnRH antagonists in In Vitro Fertilization (IVF) cycles.

Public title

Comparison the use of dydrogesterone and steroid in IVF Cycles.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile patients candidates for IVF AMH greater than 1 ng / ml First or second IVF cycle The presence of both ovaries Age less than 40 years

Exclusion criteria:

Smoking Presence of uterine anomalies Adrenal insufficiency or uncontrolled thyroid Endometriosis grade 3 or More Couples chromosomal disorder Underlying disorder that can lead to ovulatory dysfunction Repeated failure of IVF

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

A random method using a random numbers table which the researcher selects to read the numbers from top to bottom and on one of the numbers she places her finger and moves up and down and records the numbers that consider the pair numbers for the intervention group (A) and the individual numbers for the control group (B).

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

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Tehran University of Medical Sciences, Sixth Floor, Quds Building, Keshavarz Blvd

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Postal code

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Approval date

2019-02-19, 1397/11/30

Ethics committee reference number

IR.TUMS.VCR.REC.1398.172

Health conditions studied**1****Description of health condition studied**

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Number of mature oocyte

Timepoint

Two weeks after treatment

Method of measurement

Vaginal sonography

Secondary outcomes**1****Description**

LH surge

Timepoint

Two weeks after treatment

Method of measurement

Blood test

Intervention groups**1****Description**

Intervention group: Group A (study group): On the second day of the menstrual cycle, all patients undergo vaginal sonography, and in the absence of follicles greater than 10 mm, the treatment cycle begins. Patients receive oral progesterone or dydrogesterone (Duphaston, 20 mg daily, oral). Six days after the start of treatment, vaginal sonography will be performed. At the same time as starting dydrogesterone (2-3 cycles a day),

hMG (225-150 units injected daily) is prescribed. In case of appearance, 2 follicles of 18 mm and 3 follicles of 14-15 mm in ultrasound, for the trigger, decapeptide, will be administered at 0.2 cc. It is worth mentioning that taking dydrogesterone is stopped on the trigger day.

Category

Treatment - Drugs

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Description

Control group: Group B (control): hMG 225-150 injectable units daily) received in 2-3 cycles of menstruation and after administration of hMG, when the follicle reached 13 mm, the Cetrotide antagonist (GnRh, 0.25 mg), It is injected subcutaneously every 24 hours. In case of appearance, 2 follicles of 18 mm and 3 follicles in 14-15 mm in ultrasound, for a trigger, decapeptide, will be prescribed to 0.2 cc. And the antagonist (steroid) injection stops. 36-39 hours after decapeptide injection, ovule collection (OPU, Ovum Pick up) will be done in both groups. n (OPU, Ovum Pick up) will be done in both groups. The ovum obtained is categorized in terms of growth by the embryologist. And 2-3 days after the ICSI, embryos are graded by the number of cells and fragmentation by the specialist. In the next cycle, then in each patient, 2 embryos will be transmitted from the best embryos of good quality (embryos with high blastomeres and without fragmentation) and the embryo transfer will be carried out by one person from the infertility fellowship without knowledge of the patient groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic,Vali Asr Hospital,Imam Khomeini Hospital.

Full name of responsible person

Seyede Masoumeh Ghazi Mirsaeed

Street address

Keshavarz BLvd,Vali Asr Hospital,Infertility Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

Seyede Masoumeh Ghazi Mirsaeed

Position

Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Infertility

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

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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