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
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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 InVitro Fertilization (IVF) cycles.

Public title
Comparison the use of dyrogesterone 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
Street address
Tehran University of Medical Sciences, Sixth Floor, Quds Building, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
14194

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

2

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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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