Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of progesterone effect in preventing LH surge and quality of oocytes and embryos in IVF cycles with patients undergoing antagonist cycle in Shariati Hospital during 97-98

Protocol summary

Study aim
Evaluation of the effect of progesterone and LH antagonists (steroids) to prevent a sudden premature increase in LH in the ART cycle

Design
In this clinical trial study, 120 infertile women will undergo ART.

Settings and conduct
Patients undergoing IVF in Shariati hospital will be studied in two groups: one will receive the LH antagonist group (control group) and the other group will take progesterone (intervention group). We then examine the effect of these two treatments on the LH surge in IVF cycles, as well as the number of mature follicles, the number of embryos transferred, and the rate of pregnancy between the two groups being compared.

Participants/Inclusion and exclusion criteria
• Study entry criteria: The age between 18 and 35 years was a normal sperm test, a normal body mass index (18-30 kg / m2), the presence of both ovaries and the opening of the tubes. Criteria for leaving the study include: Tubal factor, severe endometriosis, hypothalamic amenorrhea, oligoasthenospermia (abnormal sperm count and shape) and severe uterine anomalies.

Intervention groups
One group receives the LH antagonist and the other group receives progesterone

Main outcome variables
LH surge - quality of oocytes - quality of embryos

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200601047630N1**
Registration date: **2020-09-18, 1399/06/28**
Registration timing: **retrospective**

Last update: **2020-09-18, 1399/06/28**
Update count: **0**

Registration date
2020-09-18, 1399/06/28

Registrant information

Name
Aida Najafian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8490 1000

Email address
anajafian@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2020-03-10, 1398/12/20

Actual recruitment start date
2018-04-04, 1397/01/15

Actual recruitment end date
2020-03-15, 1398/12/25

Trial completion date
2020-03-15, 1398/12/25

Scientific title
Comparison of progesterone effect in preventing LH surge and quality of oocytes and embryos in IVF cycles with patients undergoing antagonist cycle in Shariati Hospital during 97-98

Public title
The effect of progesterone in preventing LH surge in IVF cycles
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age between 18 and 35 years ,, a normal sperm test a normal body mass index (18-30 kg / m2) the presence of both ovaries and the opening of the tubes
Exclusion criteria:
Tubal factor severe endometriosis hypothalamic amenorrhea oligoasthenospermia (abnormal sperm count and shape) severe uterine anomalies
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
First, all patients who meet the inclusion criteria are entered into an Excel column, and then using the Rand option in this software, in the opposite column, each patient is randomly assigned the number 1 or 2. No. 1: Intervention group and No. 2: control group
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
Qods st. TUMS
City
Tehran
Province
Tehran
Postal code
1417653911
Approval date
2020-05-04, 1399/02/15
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.008

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97.9
ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
LH surge
Timepoint
End of pregnancy
Method of measurement
blood tests

2

Description
Quality of oocyte
Timepoint
End of pregnancy
Method of measurement
Blood tests

3

Description
Quality of embryo
Timepoint
End of pregnancy
Method of measurement
Blood tests

Secondary outcomes

1

Description
Clinical pregnancy
Timepoint
Day 25 of cycle
Method of measurement
Blood analysis

Intervention groups

1

Description

Intervention group: On day 2-3 of the gonadotropin cycle, including FSH with or without HMG, with medroxyprogesterone 5 mg daily, two doses are given. Vaginal ultrasounds were performed on days 9 to 10, and if 18 to 20 mm follicles were found, HCG was injected for ovulation. Then, 36 hours later, the puncture was performed. If the follicle was less than 18 mm, the Continuation of gonadotropin is done with an additional dose and medroxyprogesterone and ultrasound on the 12th day, and again if on the ultrasound of the 12th day the follicle was 18 to 20 mm, HCG is injected. If the follicle is less than 18 mm, gonadotropin and medroxyprogesterone are continued and then ultrasound is performed on day 14 and a decision is made accordingly. This process continues until day 25 of the cycle and until the follicle responds to treatment, until the day of HCG injection. And medroxyprogesterone is given and medroxyprogesterone is discontinued on the day of HCG injection.

Category

Treatment - Drugs

2

Description

Control group: In the control group, 2 to 3 cycles of gonadotropin, including FSH with or without HMG, are given on day 3, then one week later, vaginal ultrasound is performed. If the follicle is between 18 and 20 mm, HCG is injected for ovulation and then a puncture for IVF is performed 36 hours later. If the follicle is larger than 14 mm, asteroid (gonadotropin antagonist) is given with gonadotropin, and ultrasound is done again on the 12th day. If the follicle is less than 14 mm, the gonadotropin is continued with a double dose and the ultrasound is repeated on the 12th day. On day 12 ultrasound, if an 18 to 20 mm follicle is found, HCG is injected for ovulation and then a puncture is performed 36 hours later.If a 14 mm follicle is found on the ultrasound on day 12, the steroid is started, along with continued gonadotropin, and on day 14 sonography will be done again. If the follicle was less than 14 mm on day 12, the gonadotropin will be continued with an overdose, and on day 14, an ultrasound will be performed, and a decision will be made based on the sonography on day 14. This process can continue until the 25th day of the cycle, ie until the follicle responds to the drug. And patients are excluded from the study when they have a follicle less than 8 mm at the beginning, in fact, 14 mm follicle is the time of onset of steroid and follicle 18 to 20 mm is the time of onset of HCG and continues until the day of HCG gonadotropin and steroid injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Sara Pouri

Street address

Jalal Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Sahraeian

Street address

Qods St.

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Province

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Postal code

1417653911

Phone

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Email

irsw-leadinghouse@tums.ac.ir

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

Sara Pouri

Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Jalal highway
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Postal code
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Phone
+98 21 8490 1000
Email
Sarapouri65@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ayda Najafian
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Phone
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Email
anajafian@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sara Pouri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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Email
sarapouri65@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available
Informed Consent Form
Yes - There is 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
Not applicable
Title and more details about the data/document
Only a part of the data, such as information about the main consequence or the like, can be shared
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Data will only be available to researchers working at academic and scientific institutions
Under which criteria data/document could be used
For research only
From where data/document is obtainable
the email of Dr. Pouri
What processes are involved for a request to access data/document
Apply via email and specify the purpose of using the data
Comments