Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of dual trigger HCG and GnRH agonist compared to HCG only in women with poor response undergoing with antagonist protocol

Protocol summary

Study aim

Determining the effectiveness of hCG and GnRH agonist dual trigger compared to hCG alone in poor responders treated with antagonist protocol

Design

The clinical trial will have a control group with parallel groups, a blind strain (blinding only in the outcome evaluation group), randomized on 152 patients, randomized by permutation block method. Individual randomization unit

Settings and conduct

Infertile women referring to Mahdiyeh Center will be randomly divided into two groups of double stimulation and single drug stimulation if they meet the inclusion criteria. In the double stimulation group, 36 hours before egg retrieval, GnRH agonist with the brand name Sinafect (buserlin) and HCG drug with the brand name Ovitrel will be injected subcutaneously. In the control group, only Ovitrel will be injected 36 hours before oocyte collection

Participants/Inclusion and exclusion criteria

Women of reproductive age (15 to 45 years) with poor ovarian response who have at least two of the following criteria according to the Bologna criteria will be included in the study. Age over 40 years (≥40 years), history of poor response with a maximum number of three oocytes obtained after stimulation or abnormal ovarian reserve confirmed by one of the two AFC tests less than or equal to 7 or AMH less than or equal to 1.2, also if not Criteria of advanced age or abnormal ovarian reserve, women will be eligible if they have a history of two poor responses after maximal ovarian stimulation. Eligible people will enter this project if they have informed consent to enter the study. People whose spouse has azoospermia or who have PCOS themselves are excluded from the study.

Intervention groups

Intervention group: double ovarian stimulation with HCG and GnRH agonist simultaneously Control group: ovarian stimulation only with HCG

Main outcome variables

Chemical pregnancy Clinical pregnancy The number of oocyte retrived

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230506058097N1**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date

2023-06-06, 1402/03/16

Registrant information

Name

farinaz shahmoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 2628

Email address

miss.shahmoradi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of dual trigger HCG and GnRH agonist compared to HCG only in women with poor response undergoing with antagonist protocol

Public title

Comparison of the efficacy of dual trigger HCG and GnRH agonist compared to HCG only in women with poor response undergoing with antagonist protocol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women of reproductive age (from 15 to 45) with poor ovarian response who have at least two of the following criteria according to the Bologna criteria: age greater than or equal to 40 years, history of poor response with a maximum number of three oocytes obtained after stimulation or abnormal ovarian reserve confirmed by one of the two AFC test less than or equal to 7 or AMH less than or equal to 1.2 In the absence of criteria for old age or abnormal ovarian reserve, if a woman has a history of two weak responses after maximal ovarian stimulation Informed consent of clients to enter the research

Exclusion criteria:

Azospermia in the client's wife Women with polycystic ovary syndrome

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method will be permutation. Individual randomization unit and block size is 4. The intervention will be repeated twice in each block of each group. As a result, we will have 6 different blocks, each of which will be numbered arbitrarily from 1 to 6. Then, using the code of the statistical program in the R software environment version 3.6.1, 38 blocks of 4 will be produced, which will produce a sequence of size 152 in total. Using this list, patients will be assigned to the HCG stimulation or dual stimulation group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that the specialist doctor is aware of the type of intervention, it is not possible to blind the doctor in this study. According to the number of injections and the type of medicine, the patient will know in which group she belongs, so the patient will not be blinded. Blinding will only be possible for the outcome evaluation group, so that the results will be sent to this group in the form of codes A and B, and it will not be clear whether group A is the test group or the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Science

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2023-04-30, 1402/02/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.076

Health conditions studied

1

Description of health condition studied

Decreased ovarian reserve

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

2

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

3

Description of health condition studied
Poor response to ovarian stimulation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The number of oocyte obtained
Timepoint
8 to 14 days after stimulation (according to ovarian response)
Method of measurement
Observation (with microscope) and counting of eggs in the laboratory by an embryologist

2

Description
Chemical pregnancy
Timepoint
two weeks after embryo transfer
Method of measurement
Blood sampling, Measurement of BHCG Titer

3

Description
clinical pregnancy
Timepoint
eight weeks after embryo transfer
Method of measurement
Ultrasound, visualization of the gestational sac and fetal heart

Secondary outcomes

1

Description
Abortion
Timepoint
any time before 20 weeks of gestation
Method of measurement
Removal of pregnancy products before week 20

Intervention groups

1

Description
Intervention group: In this group, ovarian stimulation will be done with two GNRH agonist drugs and HCG drug. Buserlin agonist drug (Sinafect) manufactured by Sinagen company with a dose of 0.5 mg will be injected subcutaneously 36 hours before egg retrieval. The used HCG drug, Ovitrel manufactured by Merc company, with a dose of 250 micrograms, will be injected subcutaneously at the same time as the agonist drug.
Category
Treatment - Drugs

2

Description
Control group: In this group, stimulation will be done with a drug. Only the HCG drug under the brand name Ovitrel manufactured by Merc company with a dose of 250 micrograms is injected subcutaneously 36 hours before egg retrieval.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiyh hospital, Infertility center
Full name of responsible person
Farinaz Shahmoradi
Street address
Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran
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1185817311
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mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Next to Ayatollah Taleghani Hospital ,Evin , Tehran, Iran
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198396-3113
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farinaz Shahmoradi
Position
infertility fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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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