Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effectiveness of GnRH agonist stop-Antagonist protocol versus GnRH antagonist protocol in poor respondent IVF candidate patients

Protocol summary

Study aim

Comparison of the effectiveness of GnRH agonist stop-Antagonist protocol versus GnRH antagonist protocol on fertility outcomes in poor respondent IVF candidate patients

Design

This study is designed as a randomized, phase 3 clinical trial with parallel groups, and a sample size of 74 participants. The randomization method will be the block randomization method.

Settings and conduct

The study will be conducted at Arash Women's Hospital on all women undergoing IVF. Patients who signed informed consent will be randomly divided into two groups. The first group will receive the Agonist stop Antagonist porotocol and the other group received the GnRH Antagonist protocol. The random allocation and final outcome of the study will be assessed by a person who is unaware of the study process. Also, the statistician will be unaware of the study process

Participants/Inclusion and exclusion criteria

Inclusion criteria: The criteria for diagnosing poor ovarian response are two of the following:1- Age 40 or older 2 - History of poor ovarian response (POR) in the previous cycle (oocyte less than 3 in a conventional protocol), 3- Antral follicle count (AFC) less than 5-7 or Anti-Müllerian hormone (AMH) <0.5-1.1. In addition, twice poor ovarian response after maximal ovarian stimulation is sufficient reason to introduce the individual as POR without the need for other criteria. Exclusion criteria: Polycystic ovarian syndrome, Hypothalamic amenorrhea, Repeated IVF failure

Intervention groups

In the IVF process, the first group will receive the Agonist stop Antagonist protocol Group 2 will Receive the GnRH Antagonist protocol.

Main outcome variables

number of oocytes, M II oocytes, and embryos and embryo quality

General information

Reason for update

Due to the prevalence of Covid-19 and the reluctance of most patients to transfer fresh embryos in the cycle has begun, so we faced a reduction in sample size, so we requested a change in the protocol to investigate the effect of these treatments on oocyte count ,oocyte quality and embryo quality regardless of pregnancy and pregnancy outcomes

Acronym

IRCT registration information

IRCT registration number: **IRCT20110731007165N10**
Registration date: **2020-12-15, 1399/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-04, 1400/04/13**
Update count: **1**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name
Ladan Kashani
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8828 1866
Email address
kashani_ladan@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-12-10, 1399/09/20
Expected recruitment end date
2021-08-01, 1400/05/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of GnRH agonist stop-Antagonist protocol versus GnRH antagonist protocol in poor respondent IVF candidate patients

Public title
Comparison of the effectiveness of GnRH agonist stop-Antagonist protocol versus GnRH antagonist protocol in IVF candidate patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The criteria for diagnosing poor ovarian response are two of the following:1- Age 40 or older 2 - History of poor ovarian response (POR) in the previous cycle (oocyte less than 3 in a conventional protocol), 3-Antral follicle count (AFC) less than 5-7 or Anti-Müllerian hormone (AMH) <0.5-1.1. Twice poor ovarian response after maximal ovarian stimulation is sufficient reason to introduce the individual as POR without the need for other criteria.
Exclusion criteria:
Polycystic ovarian syndrome Hypothalamic amenorrhea Uterine congenital anomalies and uterine cavity abnormalities (Bicorn uterus, Unicorn uterus, Asherman, Liomyuma, Polyp, etc.) Repeated IVF failure (more than three consecutive failures) Endocrine disorders (diabetes, thyroid disease, antipolipid syndrome, cardiovascular and liver disease),
Age
From **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization list will be prepared by a statistician using the block randomization method (using the site:www.sealedenvelope.com). Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained. Then the treatment will be performed based on the kind of treatment in the envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind.
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, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-10-31, 1399/08/10
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.694

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Number of mature oocytes
Timepoint
During IVF process
Method of measurement
Embryologist opinion

2

Description
Number of mature oocytes at retrieval
Timepoint
During IVF process
Method of measurement
Embryologist opinion

Secondary outcomes

1

Description
Embryo quality
Timepoint
Embryo formation
Method of measurement
By the embryologist

2

Description
oocyte count
Timepoint
Puncture Day
Method of measurement
by embryologist

Intervention groups

1

Description
Intervention group: GnRH(0.1 mg/daily) will be injected from mid-luteal phase until mense then in the second day of menstrual cycle recombinant FSH with LH will be injected. When the size of the follicle reaches 13-14 mm, the GnRH antagonist will be injected until trigger day. When the size of the follicle will reach above 18 mm HCG will be injected and 36 hours later ovarian puncture will be performed.
Category
Treatment - Drugs

2

Description
Group2:Ovarian stimulation with GnRH will be started from 2 days of the menstrual cycle. When the size of the follicle will reach above 13-14 mm GnRH antagonist (0.2 mg/daily) will be injected until trigger day. When the size of the follicle will reach above 18 mm HCG will be injected and 36 hours later ovarian puncture will be performed. One to three embryos will be transferred on the third day and luteal phase support is performed with progesterone.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Dr.Ladan Kashani
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Email
Kashani_ladan@tums.ac.ir
Web page address
http://arash.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Sahraeyan
Street address
Tehran University of Medical Sciences, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
vcr@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

Ladan Kashani

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 8828 1866

Fax

+98 21 8895 2510

Email

kashani_ladan@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ladan Kashani

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Arash Hospital, Rashid Street, Tehran Pars

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3195

Fax

Email

Kashani_ladan@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ladan Kashani

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Arash Hospital, Rashid Street, Tehran Pars

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3195

Fax

Email

Kashani_ladan@tums.ac.ir

Web page address

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