Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of ART outcome in DUAL Trigger method in POOR RESPONDER individuals in GnRH Antagonist cycles in comparison with the usual method (Single trigger) in the infertility center of Arash Women's Comprehensive Hospital

Protocol summary

Study aim

The total number of oocytes obtained in the ovarian stimulation cycle in the DUAL trigger method compared to the single trigger method in poor responders.

Design

A clinical trial, 80 poor responder patients, with parallel groups of single trigger and dual trigger. Excel software rand function was used for randomization.

Settings and conduct

In the infertility center of Arash Women's Comprehensive Hospital. After taking a complete history, patients enter the GnRH Antagonist cycle and are divided into two groups on trigger day. The first group is treated with HCG 5000 IU and the second group is treated with DUAL trigger with HCG 5000IU and GnRH Agonist (VARIOPEPTYL 0.1 mg subcutaneously). 34 to 36 hours later the oocytes are extracted. Fertilization assessment will be performed by an embryologist. 3 days later, the embryos are transferred into the uterus. 2 weeks after transfusion, a BhCG test will be performed to determine chemical pregnancy, and if positive 5 weeks later, vaginal ultrasound will be performed to determine clinical pregnancy. a statistician who does not know how to assign individuals to groups is used.

Participants/Inclusion and exclusion criteria

Patients with POR (poor ovarian response), according to BOLOGNA criteria and candidate for ART. Inclusion criteria: ART candidate POR individuals with a normal endometrial cavity, BMI in the normal range (18-25), and age between 30 and 42 years. Exclusion criteria: grade 3 and 4 endometriosis, hydrosalpinx, endocrine disorders such as hyperprolactinemia, thyroid, adrenal problems, and azoospermia.

Intervention groups

The single trigger group will be treated with HCG and the DUAL trigger group will be treated with HCG and GnRH Agonist.

Main outcome variables

The total number of oocytes; fertilization rate; total embryo; Endometrial thickness; implantation rate; chemical pregnancy rate; clinical pregnancy rate; freeze embryo.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220409054458N1**
Registration date: **2022-06-25, 1401/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-25, 1401/04/04**
Update count: **0**

Registration date

2022-06-25, 1401/04/04

Registrant information

Name

Zakieh Musazadeh Fatidehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6739 5858

Email address

zakiyeh.1991@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ART outcome in DUAL Trigger method in POOR RESPONDER individuals in GnRH Antagonist cycles in comparison with the usual method (Single trigger) in the infertility center of Arash Women's Comprehensive Hospital

Public title

Evaluation of the outcome of ART in dual trigger method compared to the usual method in poor responder patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All poor responder patients according to BOLOGNIA criteria who are ART candidates and are in GnRH Antagonist cycle.

Exclusion criteria:

Grade 3 and 4 endometriosis Hydrosalpinx Endocrine disorders such as hyperprolactinemia, thyroid and adrenal problems Azoospermia

Age

From **30 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who entered the study were given a sealed envelope containing the number 1 or 2, group 1 of the study group (dual trigger), and group 2 of the 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

Tehran University of Medical Science, Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-03-09, 1400/12/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1489

Health conditions studied

1

Description of health condition studied

Infertility in poor responder patients

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

The number of oocytes obtained in the ovulation stimulation cycle

Timepoint

Number of oocytes obtained after ovarian puncture in the ovulation stimulation cycle.

Method of measurement

Count the number of oocytes obtained per cycle.

Secondary outcomes

1

Description

Chemical pregnancy rate

Timepoint

2 weeks after oocyte transfer into the uterus.

Method of measurement

Serum BHCG level

2

Description

Clinical pregnancy rate

Timepoint
5 weeks after oocyte transfer into the uterus.
Method of measurement
Vaginal ultrasound examination of the pregnancy sac.

Intervention groups

1

Description
Intervention group: after reaching at least 2 eggs with a diameter of 17 mm, the DUAL trigger group is treated with HCG 5000IU and GnRH Agonist (VARIOPEPTYL 0.1 mg subcutaneously) and a single dose.
Category
Treatment - Drugs

2

Description
Control group: when at least 2 17mm-diameter follicles are seen on ultrasound, the group is treated subcutaneously with a single dose of 5000IU HCG.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women's Comprehensive Hospital
Full name of responsible person
Zakiyeh Musazadeh Fatidehi
Street address
Arash Women's Comprehensive Hospital, Baghdarnia Ave., West Tehranpars
City
Tehran
Province
Tehran
Postal code
1598116539
Phone
+98 21 7788 3283
Email
Zakiyeh.1991@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Vice Chancellor for Research and Technology, Central University Organization, sixth floor, corner of Ghods Street, Keshvarz Blvd,.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
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
Zakieh Musazadeh Fatidehi
Position
reaident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash Women's Comprehensive Hospital, Baghdarnia St., West Tehranpars.
City
Tehran
Province
Tehran
Postal code
1598116539
Phone
+98 21 7788 3283
Email
Zakiyeh.1991@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Zakieh Musazadeh Fatidehi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash Women's Comprehensive Hospital, Baghdarnia Ave., West Tehranpars.
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Email
zakiyeh.1991@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zakieh Musazadeh Fatidehi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash Women's Comprehensive Hospital, Baghdarnia Ave., West Tehranpars.
City
Tehran
Province
Tehran
Postal code
1598116539
Phone
+98 21 7788 3283
Email
Zakiyeh.1991@gmail.com

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