

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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)

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+98 21 6739 5858

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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.

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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

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Arash Women's Comprehensive Hospital, Baghdarnia Ave., West Tehranpars

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

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Vice Chancellor for Research and Technology, Central University Organization, sixth floor, corner of Ghods Street, Keshvarz Blvd.,

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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

Zakieh Musazadeh Fatidehi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

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