Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparison of Dual triggering versus HCG in poor responders in ART outcomes

Protocol summary

Study aim
The aim of present study was to evaluate Dual trigger on oocyte maturation in POR patients and their ART out comes.

Design
Randomization was performed with a table of random numbers. The study was not blinded.

Settings and conduct
The study was not blinded.The study was conducted at the Yazd Infertility Research Center.

Participants/Inclusion and exclusion criteria
poor ovarian responders women (based on Bologna criteria) were included in the study. The exclusion criteria were endometrial polyps; presence of endocrine disorders (such as hyperprolactinemia, hypothyroidism), preimplantation genetic diagnosis cycles; and non fresh embryo transfer cycles.

Intervention groups
The gonadotropins were started on day 2 of the menstrual cycle. gonadotropins dose adjustments were done based on ovarian response . The GnRH antagonist was administered when mean diameter of dominant follicles reached to 13–14 mm. When at least 3 follicles with ≥18 mm diameter were seen by vaginal ultrasonography. In the first group, final oocyte maturation was done by 6500 I.U.HCG alone. In the second group triggering was done with coadministration of 6500 I.U.HCG plus 0.2 mg triptorelin simultaneous (dual trigger).Oocytes retrieval was performed 36 h after triggering through transvaginal ultrasound guided.

Main outcome variables
Chemical pregnancies were confirmed 2 weeks after embryo transfer, by positive serum HCG measurement. Clinical pregnancy is defined by the presence of gestational sac in the uterus, 4 weeks after ET.

General information

Reason for update
Updating the trial according to the last changes in methods and adding results

Acronym

IRCT registration information
IRCT registration number: **IRCT2016111628756N4**
Registration date: **2016-12-04, 1395/09/14**
Registration timing: **retrospective**

Last update: **2021-03-29, 1400/01/09**
Update count: **1**

Registration date
2016-12-04, 1395/09/14

Registrant information

Name
Elham Naghshineh

Name of organization / entity
Yazd Research and Clinical Center for Infertility

Country
Iran (Islamic Republic of)

Phone
+98 35 3824 7085

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Recruitment status
Recruitment complete

Funding source
Shahid Sadoughi University of Medical Sciences

Expected recruitment start date
2016-05-01, 1395/02/12

Expected recruitment end date
2017-10-30, 1396/08/08

Actual recruitment start date
2016-07-01, 1395/04/11

Actual recruitment end date
2016-11-30, 1395/09/10

Trial completion date
2017-02-28, 1395/12/10

Scientific title
A comparison of Dual triggering versus HCG in poor responders in ART outcomes

Public title
A comparison of Dual triggering by administration of GnRH agonist plus HCG versus HCG in poor responders in ART outcomes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
poor ovarian responders women (based on Bologna criteria) GnRH antagonist protocols fresh embryo transfer

Exclusion criteria:
endometrial polyps presence of endocrine disorders (such as hyperprolactinemia, hypothyroidism) preimplantation genetic diagnosis cycles non fresh embryo transfer cycles.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **82**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are admitted to two groups of 41 patients on the basis of permutation block method. Therapeutic tasks within the blocks are determined in such a way that they are random, but the desired allocation ratio is achieved in each block. 20 blocks of 4 and a block of 2 are considered. Generate random codes using random block allocation method which will be generated with the help of Random allocation software version 1. The first person eligible to enter the study is given number one and so on until the last person eligible for number 82 is given. Using a table generated by random allocation software by number, people receive intervention A or B. In order to be blind, the random allocation of this list is given to another person outside the study, and by sending a text message before assigning the type of treatment, the eligible person is asked according to the number, and thus the people enter the study.

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 Yazd Shahid Sadoughi University of Medical Sciences

Street address
Bouali Avenue, Safayeh,Yazd,Iran

City
Yazd

Province
Yazd

Postal code
8916977443

Approval date
2016-09-14, 1395/06/24

Ethics committee reference number
IR.SSU.RSI.REC.1395.18

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97.8

ICD-10 code description
Female infertility of other origin

Primary outcomes

1

Description
Number of metaphase II oocytes

Timepoint
After intervention

Method of measurement
number

Secondary outcomes

1

Description
number of fertilized oocytes (2PN)

Timepoint
after intervention

Method of measurement
number

2

Description
clinical pregnancy

Timepoint
28 days after transfer
Method of measurement
28 days after transfer

Intervention groups

1

Description
in intervention group co-administration of HCG and agonist used for triggering
Category
Treatment - Drugs

2

Description
in control group HCG used routinely for triggering
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd research and clinical center for infertility
Full name of responsible person
Maryam Eftekhar
Street address
Bouali/Safaieh
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8916977443
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+98 35 3824 7086
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eftekhar@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shahid saoughi university of medical science
Full name of responsible person
Masood Mirzaei
Street address
Ave Bahonar
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8916978477
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Email
masood_mirzaei@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shahid saoughi university of medical science
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
research and clinical center for infertility
Full name of responsible person
Elham Naghshineh
Position
Fellowship
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact
Name of organization / entity
Researh and clinical center for infertility
Full name of responsible person
Elham Naghshineh
Position
Followship
Latest degree
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Other areas of specialty/work
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All participant data sets are to be shared
When the data will become available and for how long
2 months after the result publication
To whom data/document is available
A journal in which the results are published
Under which criteria data/document could be used
Submission of an official application via the agent that is legally in charge
From where data/document is obtainable
Yazd Reproductive Sciences Institute
What processes are involved for a request to access data/document
Submission of an official application
Comments

Trial results

Please tick if results have been published
Yes
Summary result posting date
2021-03-29, 1400/01/09
Table of baseline comparison
Participant flow diagram
Table of variable outcomes' results
Table of adverse events
First publication date
2018-12-30, 1397/10/09
Abstract of published paper
Abstract Background The use of dual triggering in high and normal responders accompanied with better IVF cycle outcomes. Also, it has been suggested that dual triggering in poor responders can be accompanied by better results. Objective The aim of present study was to evaluate whether the Dual trigger, can improve oocyte maturation in poor responder patients based on Bologna criteria and their ART outcomes. Materials and methods All poor ovarian responder's patients underwent GnRH antagonist controlled ovarian hyperstimulation protocols in ART cycles. The participants' randomizations were done and patients divided into two groups. In the first group, final oocyte maturation was done by 6500 I.U.HCG alone. In the second group, triggering was done with coadministration of 6500 I.U.HCG plus 0.2 mg triptorelin simultaneous (dual trigger). Oocyte retrieval was performed 36 h after triggering through transvaginal

ultrasound-guided. Routine IVF/ICSI was performed as appropriate. Results The number of retrieved oocytes, number of mature oocytes (MII), number of fertilized oocytes (2PN), number of embryo formation, number of transferred embryos and embryo quality have not significant differences between the two groups ($p > 0.05$). Also, fertilization and implantation rate, chemical and clinical pregnancy did not differ between groups. Conclusion Dual triggering for final oocyte maturation in poor ovarian responders did not improve the number of mature oocytes (MII) and other ART cycle results.