Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

A comparison of Dual triggering by administration of Gonadotropin releasing hormon agonist plus human chorionic gonadotropin versus HCG in normal responders at assisted reproductive programs outcome

Protocol summary

Study aim

evaluation of dual triggering for final oocyte maturation with a single dose of GnRH-a and a standard dose of hCG in GnRH-antagonist IVF/ Intracytoplasmic sperm injection (ICSI) cycles in normal responders.

Design

The study was a phase 2 trial. Randomization was performed based on a table of computer random numbers.

Settings and conduct

The study was conducted at Yazd Infertility Research Center.The study was one-sided blind .

Participants/Inclusion and exclusion criteria

The inclusion criteria were 18< Body mass index <30 kg/m2, and age ≤42 yr with the history of infertility for at least 1 yr that were candidate for ART protocol. Our exclusion criteria were the presence of endocrine disorders such as diabetes mellitus, hyperprolactinemia, thyroid disorders, congenital adrenal hyperplasia, Cushing syndrome, polycystic ovary syndrome, congenital uterine anomaliesdisorders, repeated implantation failure, day-3 FSH concentration ≥10 IU/L or serum anti-Mullerian hormone ≤1.0 ng/mL, and azoospermia.

Intervention groups

patients began ovarian stimulation with a flexible starting dosage of recombinant FSH ranging from 150 to 225 IU on the second day of the menstrual cycle for 5 consecutive days. Once the leading follicle had reached a size of 13 mm, co-treatment with the GnRH antagonist 0.25 mg/day, was initiated. When at least two leading follicles had reached 17 mm in diameter, final oocyte maturation was triggered by either 6500 I.U. hCG alone, or by 6500 IU hCG plus 0.2 mg of triptorelin (Decapeptyl; Ferring GmbH).Oocyte retrievals were performed under transvaginal ultrasound guidance 34 to 36 hours after triggering.

Main outcome variables

The primary outcome measure was clinical pregnancy rate and the secondary outcome measures were implantation rate,chemical pregnancy , ongoing pregnancy ,OHSS rate and abortion rate.

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: **IRCT2015031221420N2**
Registration date: **2015-06-25, 1394/04/04**
Registration timing: **retrospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **2**

Registration date

2015-06-25, 1394/04/04

Registrant information

Name

Maryam Farid Mojtahedi

Name of organization / entity

Arash women hospital,clinic for infertility,Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Yazd reserch and clinical center for infertility

Expected recruitment start date
2014-03-01, 1392/12/10
Expected recruitment end date
2014-08-30, 1393/06/08
Actual recruitment start date
2014-04-01, 1393/01/12
Actual recruitment end date
2014-09-30, 1393/07/08
Trial completion date
2015-03-02, 1393/12/11

Scientific title
A comparison of Dual triggering by administration of Gonadotropin releasing hormon agonist plus human chorionic gonadotropin versus HCG in normal responders at assisted reproductive programs outcome

Public title
Dual triggering in improving assisted reproductive programs outcome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
normal responder women by tubal or male infertility factor, 18< Body mass index <30 kg/m2, and age ≤42 yr with the history of infertility for at least 1 yr that were candidate for ART protocol
Exclusion criteria:
the presence of endocrine disorders such as diabetes mellitus, hyperprolactinemia, thyroid disorders, congenital adrenal hyperplasia, Cushing syndrome, polycystic ovary syndrome, congenital uterine anomaliesdisorders, repeated implantation failure, day-3 FSH concentration ≥10 IU/L or serum anti-Mullerian hormone ≤1.0 ng/mL, and azoospermia
Age
To **42 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **223**
Actual sample size reached: **198**
Randomization (investigator's opinion)
Randomized
Randomization description
randomization was done by table of random numbers
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients were named as groups 1 and 2. And the statistical analyzer did not know the type of treatment protocol used in each group.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Yazd Research and Clinical Center for infertility
Street address
Bouali Avenue, Safayeh
City
yazd
Province
Yazd
Postal code
891687391
Approval date
2014-06-22, 1393/04/01
Ethics committee reference number
315

Health conditions studied

1

Description of health condition studied
female infertility
ICD-10 code
N97.9
ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
clinical pregnancy rate
Timepoint
28 days after transfer
Method of measurement
vaginal sonography

Secondary outcomes

1

Description
chemical pregnancy rate
Timepoint
14 days after transfer
Method of measurement
BhCG test

Intervention groups

1

Description
control group receive 6500 I.U hCG IM for triggering final oocyte maturation .
Category
Treatment - Drugs

2

Description
Intervention group receive 6500 I.U. IM hCG+triptorelin0.2mg/sc for triggering.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bouali Avenue, Safayeh
Full name of responsible person
Abbas Aflatoonian
Street address
Bouali Avenue, Safayeh
City
Yazd
Province
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Postal code
8916977443
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+98 35 3824 7085
Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shahid sadoughi university of medical sciences
Full name of responsible person
masood mirzaee
Street address
bahonar Avenue,
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Postal code
8916978477
Phone
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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 sadoughi 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
Yazd University of Medical Sciences
Full name of responsible person
Maryam Eftekhar
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Yazd University of Medical Sciences
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Maryam Eftekhar
Position
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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
Yazd reaserch and clinical center for infertility
Full name of responsible person
Maryam Farid Mojtahedi
Position
Infertility fellowship
Latest degree
Medical doctor
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
2021-03-08, 1399/12/18
Table of baseline comparison

Participants Demographics characteristics of study participants

	Group I (hCG +GnRHa) (n=99)	Group II (hCG)(n=93)	p-value	
BMI	24.13 ± 2.87	24.07 ±2.98	0.88*	
Age	30.06 ± 5.30	30.49 ± 4.79	0.54 *	
Duration of infertility (yr)	6.34 ± 3.85	6.23 ± 4.09	0.70 *	
Day-3 FSH level (IU/L)	6.59 ± 2.76	6.14 ± 2.59	0.23 *	
Infertility type (%)				
	Primary	71.3	78.4	0.49**
	Secondary	28.7	21.6	

Participant flow diagram
Table of variable outcomes' results

Comparison of clinical outcomes between two study groups

	Group I (hCG +GnRHa) (n=99)	Group II (hCG) (n=93)	p-value *
Implantation rate	11	10	0.50
Chemical pregnancy rate	(30/99) 30.3	(24/93) 25.8	0.51
Clinical pregnancy rate	(26/99) 26.3	(21/93) 22.6	0.30
Ongoing pregnancy rate	(24/99) 24.2	(20/93) 22.9	0.77
Abortion rate	(2/25) 8	(4/24) 16.7	0.35

Table of adverse events

First publication date

2017-07-01, 1396/04/10

Abstract of published paper

Abstract Background: Gonadotropin-releasing hormone agonists (GnRH-a) was increasingly used for triggering oocyte maturationfor the prevention of ovarian hyperstimulation syndrome. Studies suggest that GnRH-a might be used as a better trigger agent since it causes both Luteinizing hormone and follicle stimulating hormone release from a physiologic natural cycle. Objective: The aim of this study was to evaluate the effect of dual-triggering in assisted reproductive technology outcomes. Materials and Methods: 192 normal responder women aged ≤42 years and 18< Body Mass Index <30 kg/m2 enrolled in this single-blind randomized controlled trial. All participants received antagonist protocol. For final triggering, women randomly were divided into two groups. Group, I was triggered by 6500 IU human chorionic gonadotropin (hCG) alone, and group II by 6500 IU hCG plus 0.2 mg of triptorelin. The implantation, chemical, clinical and ongoing pregnancy, and abortion rates were measured. Results: The mean of retrieved oocytes and obtained embryos were statistically higher in the dual-trigger group (group I), but the implantation and pregnancy rates were similar in two groups. Conclusion: The results of our study did not confirm the favorable effect of dual-triggered oocyte maturation with a GnRH-a and a standard dosage of hCG as an effective strategy to optimize pregnancy outcome for normal responders in GnRH-antagonist cycles. We think that this new concept requires more studies before becoming a universal controlled ovarian hyperstimulation protocol in in vitro fertilization practice.