

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A comparison of Dual triggering by administration of Gonadotropin releasing hormone 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 $18 < \text{Body mass index} < 30$ 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 anomalies disorders, 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 anomalies disorders, 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

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aflatoonian @ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

shahid sadoughi university of medical sciences

Full name of responsible person

masood mirzaee

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bahonar Avenue,

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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 Eftekhari

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

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

Gynecology and Obstetrics

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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 +GnRH α) (n=99)	Group II (hCG)(n=93)	p-value	
BMI	24.13 \pm 2.87	24.07 \pm 2.98	0.88*	
Age	30.06 \pm 5.30	30.49 \pm 4.79	0.54*	
Duration of infertility (yr)	6.34 \pm 3.85	6.23 \pm 4.09	0.70*	
Day-3 FSH level (IU/L)	6.59 \pm 2.76	6.14 \pm 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 +GnRHα) (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 maturation for 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 $18 < \text{Body Mass Index} < 30 \text{ kg/m}^2$ 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.