

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Protocol summary

Study aim

To compare IVF results in patients with poor ovarian response included in the antagonist cycle receiving standard, double, and triple ovarian stimulation

Design

Three-arm parallel-group randomized clinical trial with 108 patients allocated into three groups, enrolled between April 2023- October 2023.

Settings and conduct

POR patients referred to the infertility department of Al-Zahra Educational Hospital, Tabriz, are assessed for eligibility to participate in the study. The eligible patients undergo controlled ovarian stimulation using antagonist protocol. After the diameter of the follicles reaches 16-18 mm, the randomization of patients into the study groups will be conducted by a nurse, using sealed envelopes, each containing a study group. Staff and patients will not be blinded. After 34- 36 hours, oocytes will be retrieved and evaluated by an embryologist. Following fertilization of the eggs and assessing embryo quality, embryo transfer will be performed and patients will undergo a pregnancy test (after two weeks) and vaginal ultrasound (after six weeks).

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent to participate in the experiment, the eligibility of patients for IVF, the presence of POR, age between 24-42 years old, BMI of 19-27, and male partner having normal sperm evaluations (WHO criteria). Exclusion criteria: The presence of uterine anomalies, severe male factor infertility, severe endometriosis, drug allergy, and medical conditions such as hypothyroidism and diabetes.

Intervention groups

POR patients are randomly divided into three groups: Group A, receiving human chorionic gonadotropin (hCG) (standard triggering), Group B, receiving hCG and decapeptide (as GnRH α) (dual triggering), and Group C,

receiving hCG, Decapeptyl, and menotropin (hMG) (triple triggering).

Main outcome variables

Primary outcome: The number of high-quality embryos

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230702058644N1**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Aliyeh Ghasemzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3177 1041

Email address

alghasemzadeh@yahoo.co.uk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-11, 1402/04/20

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Public title
Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
informed consent to participate in the study Age between 24-42 years old Body mass index of 19-27 The presence of POR (AFCl <7, AMH <1.5) Eligibility of the patient for IVF The absence of uterine abnormalities

Exclusion criteria:
Hypothalamic dysfunctions in the patient diabetes mellitus liver diseases heart diseases renal diseases epilepsy metabolic disorders

Age
From **24 years** old to **42 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be allocated to each study group by the balanced block randomization technique. The number of blocks and the size of each block are 36 and 3, respectively (A, B, and C). The order of study groups in each block will determine the order of allocations.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Comparison of patients with poor ovarian response included in the antagonist cycle during standard, dual and triple triggering in IVF outcomes

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Women's Reproductive Health Research Center, A Izahra Educational Hospital, Baghshomal square, South Artesh street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.TBZMED.REC.1402.287

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

infertilefertility

Primary outcomes

1

Description

The number of good quality embryos

Timepoint

3 days after fertilization

Method of measurement

High-quality cleavage stage embryos will have six cells or greater on day 3 and less than 10% fragmentation and symmetric blastomeres, according to the Istanbul consensus workshop.

Secondary outcomes

1

Description

number of retrieved oocytes

Timepoint

36 hours after triggering

Method of measurement

All oocyte retrievals will be performed under transvaginal ultrasound guidance and will be counted using light microscopy.

2

Description

the number of mature oocytes

Timepoint

36 hours after triggering

Method of measurement

All oocyte retrievals will be performed under transvaginal ultrasound guidance and the number of mature oocytes will be counted using light microscopy.

3

Description

the number of clinical pregnancies

Timepoint

the presence of gestation sac two weeks after a positive hCG blood test

Method of measurement

ultrasound scan

4

Description

implantation rate

Timepoint

at 6-7 weeks of pregnancy

Method of measurement

Implantation rate is calculated from the number of gestational sacs with a visible fetal heart on ultrasound scan divided by the total number of transferred embryos.

Intervention groups

1

Description

Control group: Standard triggering via the injection of human gonadotropic hormone (hCG)

Category

Treatment - Drugs

2

Description

Intervention group 1: dual triggering via hCG and Decapeptyl

Category

Treatment - Drugs

3

Description

Intervention group 2: triple triggering via administration of hCG, Decapeptyl, and menotropin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational Hospital

Full name of responsible person

Dr. Aliyeh Ghasemzadeh

Street address

Alzahra Hospital, Artesh Street, Tabriz, Iran

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5138665793

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Email

gasemzadeha@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Aliyeh Ghasemzadeh

Street address

Alzahra Hospital, Artesh Street, Tabriz, Iran

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Aliyeh Ghasemzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Aliyeh Ghasemzadeh

Position

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Latest degree

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Other areas of specialty/work

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Fax**Email**

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

Tabriz University of Medical Sciences

Full name of responsible person**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

Our data can be potentially available on October 2023.

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

None

From where data/document is obtainable

email address: zohrehmohammadi98@gmail.com

What processes are involved for a request to access data/document

Sending an email to the mentioned address and sending an identity proof that reveals the hiring academic institute is sufficient for us to share the data.

Comments