Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effect of gonadotropin-releasing hormone GnRH agonist administration with GNRH antagonist protocol on assisted reproductive methods in patients with reduced ovarian response.

Protocol summary

Study aim

Investigating the effect of gonadotropin-releasing hormone (GnRH) administration in the cycle before intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF) in poor responders.

Design

This will be a two arm parallel group design of 50 patients candidate of intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF) , single blind randomised trial, with a computer-generated randomization list with a block size of 4, with1:1 allocation.

Settings and conduct

Infertile women candidates of IVF/ICSI for different reason, having the study criteria who come to infertility clinic of Alzahra hospital will be entered into the study. Ғirst we will take an informed written consent and all part of the study will be explained to the patient. The treatment allocation will be placed in a sealed opaque envelope and picked up consecutively.

Participants/Inclusion and exclusion criteria

women with primary infertility and the criteria of poor ovarian response (based on BOLOGNA criteria) for IVF-ICSI are identified and in case of severe endometriosis or chronic disease, they will be prohibited from entering the study.

Intervention groups

In the control group, intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF) with usual gonadotropin-releasing hormone (GnRH) antagonist protocol, will be started and in the case group, patients will receive GNRH agonists in the luteal phase of pre-IVF-ICSI cycle (0.1 milligram every day for 10 to 12 days), and then the IVF-ICSI cycle will be started with the GNRH antagonist protocol.

Main outcome variables

The number and quality of the obtained oocytes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130603013566N10**
Registration date: **2022-07-31, 1401/05/09**
Registration timing: **prospective**

Last update: **2022-07-31, 1401/05/09**
Update count: **0**

Registration date

2022-07-31, 1401/05/09

Registrant information

Name

Kobra Hamdi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of gonadotropin-releasing hormone GnRH agonist administration with GNRH antagonist protocol on assisted reproductive methods in patients with reduced ovarian response.

Public title
Comparison of the effect of GnRH agonist administration with GNRH antagonist protocol on assisted reproductive methods in patients with reduced ovarian response.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Infertile women defined as poor ovarian responders according to the Bologna criteria (presence of at least two of the three Bologna criteria) Primary infertility Age 20 to 42

Exclusion criteria:
Not agreeing to participate in the study Severe oligospermia body mass index 30 and above Severe endometriosis Smoking and alcohol consumption

Age
From **20 years** old to **42 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
A computer-generated randomization list with a block size of 4, with 1:1 allocation will be used to randomize patients. In such a case, one control will be checked for each intervention and with each of the 4 patients enrolled in the study, the two groups are balanced in terms of control and intervention.50 matte and sealed envelope samples will be prepared. Randomization will be performed by a non-research person and The type of intervention will be written by random allocation on paper and placed inside the envelopes.Envelopes will be numbered from number 1 to the end.The first person will be given the first envelope and this will continue until the last desired number; There will be 25 people in group 1 and 25 people in group 2, for a total of 50 people.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the data analyst and outcome assessor will not know the type of drug. The possibility of blinding the patient and the doctor in order to respect the rights of the patients is not acceptable because it will require at least 13 painful injections under the skin with distilled water (with the same label as the drug), which is not ethically correct and has not been done in similar studies.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences

Street address
Third Floor; Central Building of Number2; Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2022-06-01, 1401/03/11

Ethics committee reference number
IR.TBZMED.REC.1401.232

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Number of eggs

Timepoint
the day of oocytes pick up

Method of measurement
Microscopic examination

2

Description
Egg quality

Timepoint
The day of oocytes pick up

Method of measurement
Microscopic examination

Secondary outcomes

1

Description
Pregnancy
Timepoint
7-6 weeks to see the gestational sac
Method of measurement
Ultrasound

Intervention groups

1

Description
Control group: In the control group IVF-ICSI with usual GnRH antagonist protocol will be started
Category
Treatment - Drugs

2

Description
Intervention group: In the case group, patients will receive GNRH agonists in the luteal phase of pre-IVF-ICSI cycle (0.1 milligram every day for 10 to 12 days), and then the IVF-ICSI cycle will be started with the GNRH antagonist protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
DR.Hamdi Kobra
Street address
Alzahra Hospital, South Artesh St.,Tabriz, iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Mohammad Samiei
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No. 2 Central Building,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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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
Vice chancellor for Research,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
Kobra Hamdi
Position
Associate Professor of Obstetrics Gynecology
Latest degree
Subspecialist
Other areas of specialty/work
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Position

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Latest degree

Subspecialist

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Person responsible for updating data

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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