Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the the effect of Dual trigger by Gonadotropin releasing hormone and Human chorionic gonadotropin versus Human chorionic gonadotropin alone on pregnancy rates in infertile women with diminished ovarian reserve undergoing intracytoplasmic sperm injection-embryo transfer cycles

Protocol summary

Study aim

To assess the effect of Duel trigger with GnRH Agonist plus Human chorionic gonadotropin on pregnancy rates in infertile women with diminished ovarian reserve.

Design

Study design: Randomized, single blind, double center, controlled clinical trial with a parallel group design of 80 patients, enrolled between October 2018 to April 2019, phase 3.

Settings and conduct

Eighty infertile women with diminished ovarian reserve will be allocated to two groups of 40 based on random number table. Patients become aware and informed of intervention but physician doesn't any information .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 20 to 45 years; normal hysterosalpingography; AMH levels < 1.5 ng/ml; antral follicular counts (AFC) < 7 in both ovaries; prior less than three failed in vitro fertilization cycles. Exclusion criteria: Normal ovarian response in ovulatory cycles or in vitro fertilization cycles.

Intervention groups

Intervention groups: Dual trigger with GnRH Agonist plus HCG on HCG injection on the day of IVF cycles. Control groups: Trigger with HCG alone on HCG injection on the day of IVF cycles.

Main outcome variables

Pregnancy rate

General information

Reason for update

The wrong date was selected by mistake and needs to be corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160815029374N4**
Registration date: **2019-05-09, 1398/02/19**
Registration timing: **prospective**

Last update: **2025-07-21, 1404/04/30**
Update count: **1**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Marzieh Zamaniyan

Name of organization / entity

Mazandaran University of Medical Sciences, Sari, Iran.

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-15, 1398/02/25

Expected recruitment end date

2019-11-16, 1398/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the the effect of Dual trigger by Gonadotropin releasing hormone and Human chorionic gonadotropin versus Human chorionic gonadotropin alone on pregnancy rates in infertile women with diminished ovarian reserve undergoing intracytoplasmic sperm injection-embryo transfer cycles

Public title
Effect of Agonist on reproduction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women aged 20 to 45 years Normal hysterosalpingography AMH levels < 1.5 ng/ml Antral follicular counts (AFC) < 7 in both ovaries Prior less than three failed in vitro fertilization cycles
Exclusion criteria:
Normal ovarian response in ovulatory cycles or in vitro fertilization cycles
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Care provider

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization, single blind, random number table
Blinding (investigator's opinion)
Single blinded
Blinding description
Randomization will be done by one ward nurse on Human chorionic gonadotropin day. Physician has not information about intervention, But patient know about it.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
No. 245, Mazandaran Universityof medical Sciences., Joibar Bolvar., Sari
City
Sari
Province
Mazandaran
Postal code
۴۳۴۷۵۷۲۴
Approval date
2019-02-20, 1397/12/01
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1398.006

Health conditions studied

1

Description of health condition studied
Diseases of the genitourinary system
ICD-10 code
N97; N98
ICD-10 code description
Female infertility; Complications associated with artificial fertilization

Primary outcomes

1

Description
Clinical pregnancy rate
Timepoint
Forth weeks after embryo transfer
Method of measurement
Utrasound

Secondary outcomes

1

Description
Oocyte recovery rate
Timepoint
48 hours after HCG injection
Method of measurement
Observation by microscopy

2

Description
Embryo rate
Timepoint
three days after oocyte recovery
Method of measurement
Observation by microscopy

3

Description

Miscarriage rate

Timepoint

Till twenty weeks after embryo transfer

Method of measurement

Ultrasound

4

Description

Oocyte quality

Timepoint

On oocyte recovery rate

Method of measurement

Observation by microscopy

Intervention groups

1

Description

Intervention group: Use of GnRH Agonist ampule (Variopeptil, 0.1 mg, SC, varian farmed, Iran) 0.2mg plus HCG (Choriomon ,5000 IU , IM, IBSA company , Switzerland) on HCG injection day.

Category

Treatment - Drugs

2

Description

Control group: Use of HCG injection alone (Choriomon ,5000 IU , IM, IBSA company , Switzerland) on HCG injection day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center, Imam Khomeini Hospital

Full name of responsible person

Marzieh Zamaniyan

Street address

233 plaque, Ground Floor, IVF ward, Imam Khomeini Hospital, Amir Mazandarani Ave, Sari.

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2

Recruitment center

Name of recruitment center

Mother Infertility Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Mazandaran University of Medical Science.

Full name of responsible person

Tahereh Abbasi

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242 Plaque, Third floor, Mazandaran University of Medical Sciences, Joybar street, Sari.

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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 of Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Marzieh Zamaniyan

Position
Assistant professor, M.D.

Latest degree
Specialist

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
Tahereh Abbasi

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Gynecology and Obstetrics

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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