

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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 Dual 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)

Phone

+98 11 3336 5724

Email address

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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 University of medical Sciences., Joibar Bolvar., Sari

City

Sari

Province

Mazandaran

Postal code

۴۳۴۷۵۷۳۲

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

Ultrasound

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
Marzieh Zamaniyan
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345 Plaque, Mother Infertility Clinic, Ground floor, Shahriar 3 Department, Farhang Street, Sari.
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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
Street address
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

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Tahereh Abbasi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

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