Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of two methods of double- trigger (GNRHa+HCG) and HCG-trigger on the final oocyte maturation in poor responder patients.

Protocol summary

Study aim
Evaluation and comparison of two Trigger methods, dubble trigger (HCG + GNRH agonist) and Trigger with HCG on oocyte maturation in patients with poor ovarian response.

Design
In this randomized clinical trial with parallel group design, 90 infertile women with poor ovarian response were divided into two intervention 1 and 2 groups. Participates don't aware of the study grouping.

Settings and conduct
This study is done at Yazd infertility clinic.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Based on the Bologna criteria, poor responder women are included in the study who have two of the following three criteria: Age more than 40 years or other risk factors for poor ovarian response; Less than three oocytes in the previous IVF cycle; Abnormal ovarian reserve test; Two episodes of poor ovarian response with maximal stimulation in previous cycles without other criteria. Exclusion criteria: Severe male factor; Untreated endocrine disorders; Severe uterine anomaly;

Intervention groups
All patients under antagonist protocol receive 250-300 unit recombinant FSH from the second day of menstrual cycle and when dominant follicle size be13-14 mm , the antagonist (cetrotide or olegalotran ampoule) is started at a dose of 250 µg daily and continues until trigger day. Intervention group 1: In this group Trigger done with 0.2 mg Deca peptil ampoule and 1000unit HCG ampoule 34-40 hours before oocyte retriveal. Intervention group 2: In this group triggers were performed by standard trigger method with 1000 HCG units approximately 36 hours before oocyte retriveal.

Main outcome variables
Follicles number; Number of recovered oocytes; Number of embryos; Pregnancy rate.

General information

Reason for update
type of blinding correction

Acronym

IRCT registration information
IRCT registration number: **IRCT20190409043207N2**
Registration date: **2019-10-22, 1398/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-11, 1400/05/20**
Update count: **3**

Registration date
2019-10-22, 1398/07/30

Registrant information

Name
Soheila Pourmasumi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3428 0086

Email address
pourmasumis871@rums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-06, 1398/06/15

Expected recruitment end date
2020-02-09, 1398/11/20

Actual recruitment start date
2019-09-06, 1398/06/15

Actual recruitment end date
2020-02-09, 1398/11/20

Trial completion date
2020-08-22, 1399/06/01

Scientific title
Comparison of two methods of double- trigger (GNRHa+HCG) and HCG-trigger on the final oocyte maturation in poor responder patients.

Public title
Comparison of the oocyte quality in patients with poor ovarian response undergone two triggering methods.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age more than 40 years or other risk factors for poor ovarian response. Less than three oocytes in the previous IVF cycle Abnormal ovarian reserve test Two histories of poor ovarian response following receiving maximal stimulation

Exclusion criteria:
Severe male factor Untreated endocrine disorders Severe uterine anomaly

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **122**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization selection of the patients, through the site www. randomization.ir, we create a list of random numbers for assigning patients to treatment groups (A&B). Then, the number of each patient, which is according to the entrance number to the clinic, is written on the envelope, and the type of treatment that was randomly selected through the mentioned site is put in the envelope. Also, thick envelopes are used in the aim to not be identifiable, the type of treatment for each patient, in the envelope, by the people who make the random assignment of the patient. In this way, each patient, who refer for giving treatment, comes with an envelope containing the type of assigned treatment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address
Bouali Ave, Safayeh.

City
Yazd

Province
Yazd

Postal code
8916877391

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.SSU.RSI.REC.1398.011

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N98.9

ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
Clinical pregnancy rate

Timepoint
Four weeks after positive beta hCG

Method of measurement
Fetal heart activity by trans-vaginal ultrasonography

Secondary outcomes

1

Description
Biochemical pregnancy rate

Timepoint
14 days after embryo transfer

Method of measurement
Positive B-HCG

2

Description
Implantation rate

Timepoint
4 weeks after embryo transfer

Method of measurement
It is defined as the numbers of gestational sacs that detected throughout sonography per number of embryos transferred (100 embryo)

3

Description
Abortion rate
Timepoint
Before 20th weeks of gestation.
Method of measurement
Observation and counting

4

Description
COC counting
Timepoint
The day of oocyte puncture
Method of measurement
Counting

5

Description
MII oocyte number
Timepoint
The day of puncture
Method of measurement
Counting

6

Description
2PN number
Timepoint
1 day after fertilization
Method of measurement
Counting

7

Description
Estradiol level
Timepoint
In the day of hCG injection
Method of measurement
Biochemical measurements in the blood

8

Description
Embryo grading
Timepoint
3 days after puncture
Method of measurement
Observation and grading according to the embryo references

Intervention groups

1

Description
Intervention group: Intervention group: Trigger with 0.2 mg deca peptil ampoule and 10000 HCG ampoule 40 and 34 hours before oocyte retrieval.
Category
Treatment - Drugs

2

Description
Intervention group: Trigger by standard method with 10000units HCG 36 hours before oocyte retrieval.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Research and Clinical Center for Infertility
Full name of responsible person
Prof Abbas Aflatoonian
Street address
Bu Ali Ave, Safaeieh
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
M_mortazavi58@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Masoud Mirzaee
Street address
Bu Ali Ave- Safaeieh
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
M_mortazavi58@yahoo.com
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Dr maryam Mortazavi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Bu Ali Ave, Safaeieh
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
m_mortazavi58@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Maryam Mortazavi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Bu Ali Ave- Safaeieh
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
m_mortazavi58@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Maryam Mortazavi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Bu Ali Ave- Safaeieh
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
m_mortazavi58@yahoo.com

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 data obtained from this study will be released after being unidentified studies participants
When the data will become available and for how long
Get started 6 months after publishing the study results
To whom data/document is available
The findings of this study will be accessible for all individuals
Under which criteria data/document could be used
To improve pregnancy outcomes of the infertility centers
From where data/document is obtainable

Yazd Research and Clinical Center for Infertility

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

Receiving the author's confirmation and obtaining approval from the director of the Yazd Infertility Clinic

Comments