Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
Determination and comparison of clinical pregnancy rate in two study groups

Design
Randomized clinical trial with 1 and 2 studt group with parallel therapies

Settings and conduct
This study is carried out at Yazd Research and clinical Center for Infertility (Research Institute for Reproductive Sciences). All patients under antagonist protocol receive 150-225 unit recombinant FSH from the second day of menstrual cycle and when dominant follicle size be18 mm or greater, patients in group A Trigger with 0.2 mg Deca peptil ampoule and 6500 unit HCG ampoule 34-40 hours before oocyte retriveal and in group B triggers were performed by standard trigger method with 6500 HCG units approximately 36 hours before oocyte retriveal.

Participants/Inclusion and exclusion criteria
In this study, 130 infertile normal responderwomen (age <42 kg BMI <30 Kg /m2. FSH> 10 on third menstrual cycle day and AMH <1 and no evidence of polycystic ovary syndrome) included. other inclusion criteria are(lack of severe male infertility factor, uterine anomaly and untreated thyroid disorder), and also estradiolon triggers day must be between 500 and 3000 pg / ml randomly divided into groups A and B Split.

Intervention groups
All patients under antagonist protocol receive 150-225 unit recombinant FSH from the second day of menstrual cycle and when dominant follicle size be18 mm or greater, patients in group A Trigger with 0.2 mg Deca peptil ampoule and 6500 unit HCG ampoule 34-40 hours before oocyte retriveal and in group B triggers were performed by standard trigger method with 6500 HCG units approximately 36 hours before oocyte retriveal.

Main outcome variables
Number of follicles; number of recovered oocytes; number of canceled cycles; number of embryo; embryo grading; transmitted embryos; pregnancy rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190409043207N3**
Registration date: **2019-12-22, 1398/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-22, 1398/10/01**
Update count: **0**

Registration date
2019-12-22, 1398/10/01

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
2020-01-05, 1398/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

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

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

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
normal responder women Age less than 42 years BMI <30 Kg / m2 Estradiol Trigger Doses between 500 and 3000 pg / ml

Exclusion criteria:
Severe male factor Untreated thyroid disorders Severe uterine anomaly Existence of pco criteria FSH> 10 days of the third menstrual cycle and AMH <1 BMI less than 18 and more than 35 Predicting the the chance of of ovarian hyper stimulation syndrom(OHSS) Hyperprolactinemia Endocrine Disorders Congenital adrenal hyperplasia

Age
From **18 years** old to **42 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method was simple randomization, so this method is based on a random number table. Thus, we assign 65 odd number to the case group and 65 even number to the control group. The patient randomly assigned to the one group by selecting one number.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. The participant know abot study design but are blind and don't aware from grouping. Data analysor don't knows the groups as A and B and is unaware of type of treatment in each group.(double blind).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
SShahid 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.1398.010

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
Number of follicles

Timepoint
From the tenth day of the cycle

Method of measurement
sonography

2

Description
Number of recovered oocytes

Timepoint
Oocyte recovery day

Method of measurement
observation

3

Description
Number of canceled cycles

Timepoint
Oocyte recovery day

Method of measurement
observation

4

Description
Number of embryo
Timepoint
2 days after Oocyte recovery
Method of measurement
observation

5

Description
embryo grading
Timepoint
3 days after Oocyte recovery
Method of measurement
observation

6

Description
Number of transfered embryo
Timepoint
embryo transfere day
Method of measurement
observation

Secondary outcomes

1

Description
Chemical pregnancy rate
Timepoint
14 days after embryo transfer
Method of measurement
positive B-HCG

2

Description
clinical pregnancy rate
Timepoint
4 weeks after embryo transfer
Method of measurement
fetal heart rate in sonography

Intervention groups

1

Description
Intervention group: Trigger with 0.2 mg deca peptil ampoule and 6500 HCG ampoule 40 and 34 hours before oocyte retriveal.
Category
Treatment - Drugs

2

Description
Intervention group: Trigger by standard method with 6500 units HCG 36 hours beforeo oocyte retriveal.
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
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
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
Medical doctor
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
دکتر مریم مرتضوي
Position
Associate professor
Latest degree
Medical doctor
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
Medical doctor
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 study results
To whom data/document is available
The findings of this study will be accessible to all individuals.
Under which criteria data/document could be used
To improve pregnancy outcomes in infertility clinics
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