

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 study 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 be 18 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 retrieval and in group B triggers were performed by standard trigger method with 6500 HCG units approximately 36 hours before oocyte retrieval.

Participants/Inclusion and exclusion criteria

In this study, 130 infertile normal responder women (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 estradiol on 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 be 18 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 retrieval and in group B triggers were performed by standard trigger method with 6500 HCG units approximately 36 hours before oocyte retrieval.

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 about study design but are blind and don't aware from grouping. Data analyser 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 transferred 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 retrieval.

Category

Treatment - Drugs

2**Description**

Intervention group: Trigger by standard method with 6500 units 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

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 مرتضوی

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