

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

A comparison between the effect of two kinds of triggering with GnRh agonist in PCOS patients treated by antagonist protocol for ART on oocyte and embryo quality

Protocol summary

Study aim

The comparison of oocyte maturity rate between the two triggering methods using GnRH agonist protocol

Design

In a randomized , parallel groups, phase 2 clinical trial with control group, 112 patients with PCOS undergoing GnRH antagonist protocol were randomly divided into two groups of double and single dose triggering method using random number table.

Settings and conduct

This study was performed on 112 PCOS patients referred to Yazd Research and Clinical Center for Infertility. The patients received GnRH antagonist group for ovulation induction. On the oocyte triggering day patients were randomly divided into two groups. In the case group oocyte triggering was performed with a single dose of decapeptyl 0.2 mg and after 12 hours the second dose of decapeptyl 0.1 mg was injected. The control group was triggered by only one dose of decapeptyl 0.2 mg.

Participants/Inclusion and exclusion criteria

Inclusion criteria: PCOS women aged 20-38 years with body Mass Index > 18 and < 30 and serum estradiol level more than 3000 pg/ml on triggering day and ovarian stimulation with GnRH antagonist protocol
Exclusion criteria: Sever endometriosis, Sever male factor infertility, Uterine anomaly and Metabolic disease

Intervention groups

The cases were triggered by decapeptyl 0.2 milligram at first and secondly a dose of decapeptyl 0.1 milligram after 12 hours . The control group was triggered by one dose of decapeptyl 0.2 milligram.

Main outcome variables

Oocyte maturity rate

General information

Reason for update

Updating the trial regarding actual sample size, actual recruitment start and end dates

Acronym

IRCT registration information

IRCT registration number: **IRCT20181211041930N1**

Registration date: **2018-12-22, 1397/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-14, 1400/01/25**

Update count: **1**

Registration date

2018-12-22, 1397/10/01

Registrant information

Name

Masrooreh Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7085

Email address

masroorehoseini@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-10, 1397/09/19

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

2018-12-15, 1397/09/24

Actual recruitment end date

2019-05-30, 1398/03/09

Trial completion date

2019-07-30, 1398/05/08

Scientific title

A comparison between the effect of two kinds of triggering with GnRh agonist in PCOS patients treated by antagonist protocol for ART on oocyte and embryo quality

Public title

The effect of two kinds of triggering with GnRh agonist in antagonist protocol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

PCOS women based on Rotterdam criteria who were candidate for ART Serum estradiol level more than 3000 pg/ml on triggering day Ovarian stimulation with GnRH antagonist protocol Age between 20-38 years Body Mass Index > 18 and < 30

Exclusion criteria:

Sever endometriosis Sever male factor infertility Uterine anomaly Metabolic disease

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

At first we choose 112 patients who met the inclusion criteria ,and 1 to 112 numbers were assigned to each participants consecutively. The patients were divided into two 56-participant groups by using random allocation soft ware and random codes generation. At the time of patients' visit, they were allocated into two groups based on their random generated numbers.

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 Science

Street address

Bou_Ali Ave, Safayieh

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2018-12-02, 1397/09/11

Ethics committee reference number

IR.SSU.RSI.1397.022

Health conditions studied

1

Description of health condition studied

Triggering with different doses of GnRh a in PCO patients

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

The number of mature oocytes (MII)

Timepoint

After oocyte retrieval

Method of measurement

Counting mature oocyte under microscopy

2

Description

Number of 2PNs

Timepoint

16 hours After fertilization

Method of measurement

Counting 2PNs under microscopy

3

Description

OHSS developing

Timepoint

Days 4 and 7 post oocyte pick-up

Method of measurement

Measuring ovarian size, presence of free fluid in Douglas.

Secondary outcomes

1

Description

Embryos quality and embryo count

Timepoint

48 hours after fertilization

Method of measurement

Assessment under microscopy by embryologist.

Intervention groups

1

Description

Intervention group: The intervention group were triggered by injection of decapeptyl 0.2 mg, following by the second dose of decapeptyl 0.1 mg after 12 hours.

Category

Treatment - Drugs

2

Description

Control group: The control group was triggered by decapeptyl 0.2 mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Clinical Center for Infertility

Full name of responsible person

Abbas Aflatoonian

Street address

Bou-Ali Ave, Safaeyeh

City

Yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Email

abbas_aflatoonian@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Bahonar Ave

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3725 8770

Email

Info@ssu.ac.ir

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

Masrooreh Hoseini

Position

Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Bou-Ali, Safaeyeh, Research and Clinical Center for Infertility

City

Yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Email

masroorehoseini@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Abbas Aflatoonian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Bou_Ali, Safaeyeh, Research and Clinical Center for Infertility

City

Yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Email

abbas_afatoonian@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Masrooreh Hoseni

Position

Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Bou_Ali Ave, Safaeyeh, Research and Clinical Center for Infertility

City

Yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Email

masroorehoseini@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

The study protocol, the statistical analysis map, the clinical study report will be available after the publishing of the article .

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use in the retrospective studies

From where data/document is obtainable

Yazd Research and Clinical Center for Infertility

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

Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data.

Comments