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
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+98 35 3824 7085
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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
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8916978477
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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
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Professor
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Person responsible for updating data

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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