

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trail of comparison of pregnancy outcome in delay gonadotropin releasing hormone(GnRH) antagonist versus microdose flare GnRH agonist protocol in infertile poor ovarian responder women undergoing in vitro fertilization/ intra cytoplasmic sperm injection (IVF/ ICSI) cycles

Protocol summary

Summary

This is a clinical trial phase 3 study which compares pregnancy outcome in delay gonadotropin releasing hormone(GnRH) antagonist versus microdose flare GnRH agonist protocol in infertile poor ovarian responder women undergoing in vitro fertilization/ intra cytoplasmic sperm injection (IVF/ ICSI) cycles. This study is conducted on 100 infertile women with poor ovarian response without sever male factor between 18 to 42 years old who admit to Yazd research and clinical center between September 2016 and December 2016 who candidate for IVF/ICSI cycles. A microdose GnRH agonist flare up to 50 patients (group 1) and a delay GnRH antagonist protocol to another 50 patients (group 2) are applied randomly with randomized allocation software. Ovarian stimulation according to protocols is initiated in both groups. Final oocyte maturation is triggered in both groups with 10,000 unit human chorionic gonadotropin (HCG) when the largest two follicles attain a mean diameter of 17 millimeter. Oocyte retrieval is performed under transvaginal ultrasound guidance 36 hours after HCG administration. In this two groups dominant follicles, mature oocytes retrieved, fertilization rate and clinical pregnancy rate are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071628950N1**

Registration date: **2016-10-20, 1395/07/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-20, 1395/07/29

Registrant information

Name

Nosrat Neghab

Name of organization / entity

Research and Clinical center for Infertility, Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7085

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trail of comparison of pregnancy outcome in delay gonadotropin releasing hormone(GnRH) antagonist versus microdose flare GnRH agonist protocol in infertile poor ovarian responder women undergoing in vitro fertilization/ intra cytoplasmic sperm injection (IVF/ ICSI)

cycles

Public title
Effect of treatment protocol on pregnancy outcome in infertile poor ovarian responder women undergoing in vitro fertilization/ intra cytoplasmic sperm injection (IVF/ ICSI)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: infertile women between 18 to 42 years old with ≤ 8 antral follicle count in bilateral ovaries; and or patients with basal follicle stimulating hormone (FSH) ≥ 9 milli unit per milliliter; and or patients with a history of cancelled invitro fertilization(IVF) cycle ≤ 3 dominant follicles; and or ≤ 500 pico mole per liter estradiol (E2) levels at human chorionic gonadotropin(hCG) administration day. Exclusion criteria: patients under 18 years old or over 42 years old; patients with sever male factor

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomized allocation with computerized program we divide the patients randomly in intervention and control groups with table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Bouali Avenue, Safayeh, Yazd, Iran

City

Yazd

Postal code

8916877391

Approval date

2016-06-12, 1395/03/23

Ethics committee reference number

IR.SSU.RSI.REC.1395.3

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility ,unspecified

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

28 days after transfer

Method of measurement

Vaginal sonography

Secondary outcomes

1

Description

Number of mature oocytes

Timepoint

Oocyte pucture day

Method of measurement

Number of M2 oocytes

Intervention groups

1

Description

In interventional group delay Gn RH antagonist protocol for controlled ovarian hyper stimulation is used. All patients are received estrogen tablet 2 milligram daily starting in mid luteal previous cycle (21 cycle) for 10 days. Cetrotide (Cetorelix, Switzerland) 0.25 sub cutaneous daily is administered after cessation of estradiol. Cetrotide is continued for 7 days and ovarian stimulation is started after 7 days of GnRH antagonist pretreatment with 300 unit gonadotropin(Gonal f, Sorono, Switzerland).The women are controlled with serial sonography after five day ovarian stimulation. When a lead follicle reaches 12 millimeter, Cetrotide is initiated again and is continued until the human chorionic gonadotropin (HCG, Pregnyle,Netherlands) trigger. Final oocyte maturation is triggered in both groups with 10,000 unit HCG when the largest two follicles attain a mean diameter of 17 millimeter. Oocyte

retrieval is performed under transvaginal ultrasound guidance 36 hours after hCG administration

Category

Treatment - Drugs

2

Description

In control group, microdose flare Gn RH agonist protocol for controlled ovarian hyperstimulation is used. On the second day of menstrual cycle Buserlin acetate (Cinnafact, Cinnagen) 50 micro gram twice daily sub cutaneous is initiated which continued until trigger day. After 2 days, stimulation with a gonadotropin (Gonal f, Sorono, Switzerland) 300 unit daily is begun. The women are controlled with serial sonography since 9th day of cycle. The dose and follow up are individualized according to the ovarian response. Final oocyte maturation is triggered with 10,000 unit human chorionic gonadotropin (HCG, Pregnyl, Netherlands) when the largest two follicles attain a mean diameter of 17 millimeter. Oocyte retrieval is performed under transvaginal ultrasound guidance 36 hours after hCG administration.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Research and Clinical Center for Infertility
Shahid Sadoughi University of Medical Sciences

Full name of responsible person

DR Robab Davar

Street address

Bouali Avenue, Safayeh, Yazd, Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Sadoughi
University of Medical Sciences

Full name of responsible person

DR Robab Davar

Street address

Bahonar square, Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahid Sadoughi University

of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd Research and Clinical Center for Infertility
Shahid Sadoughi University of Medical Sciences

Full name of responsible person

DR Nosrat Neghab

Position

Obstetrician and gynecologist fellowship of infertility
and IVF (studying)

Other areas of specialty/work

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Yazd Research and Clinical Center for Infertility
Shahid Sadoughi University of Medical Sciences

Full name of responsible person

DR Nosrat Neghab

Position

Obstetrician and gynecologist fellowship of infertility
and IVF(studying)

Other areas of specialty/work**Street address**

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty