

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of ovarian response to ovulation induction after "Minidose long agonist" and "GnRH-agonist/GnRH-antagonist" protocols among poor responder infertile women who undergoing assisted reproductive technology

Protocol summary

Summary

The purpose of this study is to compare the ovarian response to ovulation induction after "Minidose long agonist" and "GnRH-agonist/GnRH-antagonist" protocols among poor responder infertile women. The sample includes all infertile women with at least two episodes of poor responses following maximal stimulation or at least two of the following three conditions: 1- Advanced maternal age (40 years old or greater) 2- A history of IVF failure (retrieved 3 oocytes or lesser) 3- An abnormal ovarian reserve test (Antral Follicle Count 5 or lesser in early follicular phase or Antimulerian hormone less than 1mIU/ml). Infertile couples who undergo TESE (Testicular Sperm Extraction) or PESA (Percutaneous Epididymal Sperm Aspiration); uterine myoma with 4cm size or greater; endometriosis (stage 3 or 4); or maternal age greater than 43 years old are excluded from the current study. The sample includes 100 patients divided in two groups randomly. First group involves patients receiving minidose long agonist GnRH prior to ovulation induction and the second group is the patients undergoing ovulation induction with mixed agonist and antagonist GnRH protocol. After observing at least two 18 mm follicles in trans vaginal ultrasound, hCG (10000 units and IM) is injected. The following step is ovarian puncture guided by trans vaginal ultrasound under general anesthesia 36 hours later. Trans cervical embryo transfer is performed 3 days after the puncture. In this study, the following outcomes are compared between two groups: number of retrieved oocytes, dominant follicles, embryos; quality of embryos; the rate of fertilization, chemical and clinical pregnancy, cancellation of ovulation induction cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106026689N1**

Registration date: **2014-05-16, 1393/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-16, 1393/02/26

Registrant information

Name

Sedigheh Hosseinimousa

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2013-08-17, 1392/05/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ovarian response to ovulation induction after "Minidose long agonist" and "GnRH-agonist/GnRH-antagonist" protocols among poor responder infertile women who undergoing assisted reproductive technology

Public title

Choice of Treatments for Ovulation Induction Among Poor Responders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Infertile women with at least two episodes of poor responses following maximal stimulation or at least two of the following three conditions: 1- Advanced maternal age (40 years old or greater) 2- A history of IVF failure (retrieved 3 oocytes or less) 3- An abnormal ovarian reserve test (Antral Follicle Count 5 or lesser in early follicular phase or Antimulerian hormone less than 1mIU/ml) Exclusion Criteria: 1-Male infertility which needs interventions such as TESE (Testicular Sperm Extraction) or PESA (Percutaneous Epididymal Sperm Aspiration) 2- Endometriosis (stage 3 or 4) 3- Uterine myoma with 4cm size or greater 4- maternal age greater than 43 years old

Age

From **20 years** old to **43 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)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

All volunteers with inclusion criteria are asked to participate in the current study if agreed; an informed consent form is signed. She is randomly assigned to one of two groups based in Bernoulli distribution. Initially, patients and physicians were blinded to the treatment group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ethics Committee, Tehran University of Medical Sciences, Poorsina Street, Tehran

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Postal code

1417653761

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

90-04-30-15625-52546

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

The number of retrieved oocytes

Timepoint

The day of oocyte retrieval

Method of measurement

Invert Microscope, Diaphot 300, Nikon, Japan

Secondary outcomes

1

Description

Chemical Pregnancy

Timepoint

19 days after oocyte retrieval

Method of measurement

β hCG titration

2

Description

The number of dominant follicles

Timepoint

48 hours prior to oocyte retrieval

Method of measurement

Transvaginal ultrasonography

3

Description

The number and quality of embryos

Timepoint

48 hours after oocyte retrieval

Method of measurement

Invert Microscope, Diaphot 300, Nikon, Japan

4

Description

Clinical pregnancy rate

Timepoint

33 days after oocyte retrieval

Method of measurement

observed gestational sac in transvaginal sonography

5

Description

Fertilization Rate

Timepoint

The day after oocyte retrieval

Method of measurement

(Total number of embryos/ Total number of injected oocytes)* 100

6

Description

Cancellation rate of cycle

Timepoint

Any time

Method of measurement

the number of cycles not resulted in oocyte retrieval

Intervention groups

1

Description

First group, Minidose Agonist, receives GnRH Agonist (Buserelin, Aventis, Germany) 50 µg subcutaneously from midluteal cycle (21th day). Ovarian stimulation is conducted by using Gonal F (Serono, Switzerland) 375-600IU daily, for one week. Then Gonal F is replaced by HMG (Ferring, Germany, 300-600IU daily) until the observation of 18mm follicles in transvaginal ultrasound. For visualizing follicular development, trans vaginal ultrasound (Sonoline G20; Siemens Medical Solutions, California, USA) is performed every 3 days. After the observation of at least two 18mm follicles, HCG (Ferring Co, Germany, 10000IU and IM) is injected and after 36 hours oocyte retrieve is performed under general anesthesia. Three days after fertilization technique, performed through intracytoplasmic sperm injection (ICSI), trans cervical embryo transfer will be carried out. Detection of pregnancy is through serum BhCG analysis, 16 days after embryonic transfer and the clinical pregnancy is detected by the aid of trans vaginal ultrasound, two weeks later when the pregnancy sac is detected. Main outcome is the number of oocytes

retrieved. The number of dominant follicles, embryos; quality of embryos; the rate of fertilization, chemical and clinical pregnancy are compared between two groups.

Category

Treatment - Drugs

2

Description

Second group receives Decapeptide 0.1mg (Ferring, Germany) in 3 consecutive days from the first day of menses. In the third day of menses ovarian stimulation is conducted by using Gonal F (Serono, Switzerland) and HMG (Ferring, Germany) 375-600IU daily. When the 14mm follicles is observed in transvaginal ultrasound GnRH antagonist (Cetrorelix, Ferring, Germany) 0.25mg daily is added. For visualizing follicular development, trans vaginal ultrasound (Sonoline G20; Siemens Medical Solutions, California, USA) is performed every 3 days. After the observation of at least two 18mm follicles, HCG (Ferring Co, Germany, 10000IU and IM) is injected and after 36 hours oocyte retrieve is performed under general anesthesia. Three days after fertilization, technique performed through intra cytoplasmic sperm injection (ICSI), trans cervical embryo transfer will be carried out. Detection of pregnancy is through serum BhCG analysis, 16 days after embryonal transfer and the clinical pregnancy is detected by the aid of trans vaginal ultrasound, two weeks later when the pregnancy sac is detected. Main outcome is the number of oocytes retrieved. The number of dominant follicles, embryos; quality of embryos; the rate of fertilization, chemical and clinical pregnancy, cancellation are compared between two groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Unit, Shariati Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

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Medical Sciences, Keshavarz Boulevard, Tehran

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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, Tehran 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**

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Web page address**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