Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

City
Tehran

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
βhCG 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 (Bucerelin, 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 Decapeptyle 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
Dr Sedighe Hoseinimosa
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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
Dr Akbar Fotouhi

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Vice Chancellor for Research, Tehran University of 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

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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