

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparision of ART(IVF or ICSI) outcome in two different induction ovulation protocols: Gonal-F versus Fostimon, in infertile patients with PCOD, referring to Valiasr hospital during 1387-1388

Protocol summary

Summary

This randomized clinical trial study was done on 160 PCOS patients and infertile candidates ART (Assisted Reproduction Technique) in the infertility clinic of Vali-Asr Hospital during the years 1387 to 1388 after obtaining the consent letter. Inclusion criteria: age(20-35y), having at least 2 PCO criteria (oligo or anovulation, oligo or amenorrhea, hyperandrogenemia, hirsutism, volum of ovary>10ml, poly cystic ovaries), normal karyotype of couples. Exclusion criteria: age>35 or<20y, abnormal karyotype, other diseases causing anovulation(hypo or hyper gonadotropic hypogonadism, Cushing, hyperprolactinemia.), other causes of infertility, not having PCO criteria, history of poor response to gonadotropin induction. Patients were randomly divided into two 80-member groups. Group A received 150 units of recombinant FSH (Gonal-F) daily& group B, 150 units of urinary FSH (Fostimon). Patients were evaluated with sonography in order to measure the size of follicles & adjust gonadotropin dose. Demographic data and quantitative variables studied including (follicles, obtained immature oocytes, oocytes, the embryos transferred, clinical & chemical pregnancy) were inserted in questionnaire and evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901193636N1**

Registration date: **2010-04-08, 1389/01/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-08, 1389/01/19

Registrant information

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Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-03-20, 1387/01/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of ART(IVF or ICSI) outcome in two different induction ovulation protocols: Gonal-F versus Fostimon, in infertile patients with PCOD, referring to Valiasr hospital during 1387-1388

Public title

Comparision of ART(IVF or ICSI) outcome in two different induction ovulation protocols: Gonal-F versus Fostimon, in infertile patients with PCOD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age(20-35y), having at least 2 PCO criteria (Oligo or anovulation, oligomenorrhea or amenorrhea, hyperandrogenemia, hirsutism, volum of ovary>10ml, poly cystic ovaries), normal karyotype of couples, Exclusion criteria: age>35 or<20y, abnormal karyotype, other diseases causing anovulation(hypo or hyper gonadotropic hypogonadism, Cushing, hyperprolactinemia.), other causes of infertility, not having PCO criteria, history of poor response to gonadotropin induction.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University Of Medical Sciences, Ethics committee

Street address

Poorsina Avenu

City

Tehran

Postal code

Approval date

2008-06-06, 1387/03/17

Ethics committee reference number

835

Health conditions studied

1

Description of health condition studied

female infertility

ICD-10 code

N97

ICD-10 code description

female infertility

2

Description of health condition studied

polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

polycystic ovarian syndrome

Primary outcomes

1

Description

rate of clinical pregnancy

Timepoint

2 weeks after positive Bhcg

Method of measurement

sonography

2

Description

rate of chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

serum bhcg

Secondary outcomes

1

Description

Rate of abortion

Timepoint

Every 2-4 weeks, based on patients' signs

Method of measurement

sonography

2

Description

Ongoing pregnancy

Timepoint

12 weeks after positive BHCG

Method of measurement

sonography

3

Description

Numbers of follicles >18mm

Timepoint

2-3 days after gonadotropin injection

Method of measurement

sonography

4

Description

Numbers of oocytes

Timepoint

in day of pick up

Method of measurement

Counting picked up oocytes

5

Description

Numbers of embryos

Timepoint

day of embryos transfer, 3 days after pick up

Method of measurement

counting embryos

6

Description

Endometrial thickness

Timepoint

At the day of HCG (Amp.) injection

Method of measurement

sonography

7

Description

Total numbers of gonadotropin ampoule administered

Timepoint

At final cycle

Method of measurement

Counting of ampoule administered

8

Description

Quality of embryo

Timepoint

3 days after pick up

Method of measurement

by embryologist (grad A, B, C)

9

Description

Numbers of embryos transferred

Timepoint

day of embryo transfer

Method of measurement

counting of embryos transferred

Intervention groups

1

Description

Group A, Gonl-F injection

Category

Treatment - Drugs

2

Description

Group B, Fostimon injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital, infertility center

Full name of responsible person

Maryam Baghery, Shahrzad Sheikhhasani

Street address

Bagherkhan Aven. Emam Khomeini hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

khorrani

Street address

Poorsina Aven.

City

Tehran

Grant name

پایان نامه

Grant code / Reference number

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

Yes

Title of funding source

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

Emam khomeini hospital

Full name of responsible person

Shahrzad. Sheikhhasani

Position

resident of obstetrics & gynaecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Univrsity OF Medical Sciences

Full name of responsible person

Dr.Farnaz Sohrabvand

Position

specialist in Ob.Gyn. & infertility

Other areas of specialty/work

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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