

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparative study on the pregnancy outcomes of IVF between GnRH-a and OCP in women with moderate and sever endomethriosis.

Protocol summary

Summary

The informed consent was taken from the patients before the beginning of the study. In group 1 the patients takes OCP for two month before IVF then received a standard controlled ovarian hyperstimulation (COH) regimen. It consisted of subcutaneous injections of 0.05 to 0.1 mg/day of a GnRH agonist (Diphereline 0.1 mg) for 7 to 10 days in the mid-luteal phase for pituitary down-regulation, and exogenous ovarian stimulation with gonadotropin was initiated on the second or third day after the onset of menstruation. In group 2 the patients received a 3.75-mg intramuscular injection of a GnRH agonist (Diphereline) twice, at a 28 days' interval. Controlled ovarian hyperstimulation was initiated within 10 days of the last GnRH agonist injection. Ovarian stimulation was achieved using FSH (Gonal-F ;) and/or human menopausal gonadotropin. Human chorionic gonadotropin (hCG) was administered to trigger egg maturation when at least 1 follicle achieved a mean diameter of 17 mm. The patients were scheduled for oocyte retrieval 34 to 36 hours after the hCG injection. Indications and techniques for oocyte aspiration, oocyte and embryo culture, insemination, intracytoplasmic sperm injection, and embryo transfer were based on the routine of the center. Embryos were transferred at the 4- or 8- cell stage. Response to controlled ovarian hyperstimulation and IVF- ET cycle outcome were compared between groups. Clinical pregnancy was defined as an elevated serum hCG and the presence of a gestational sac on transvaginal ultrasound. Implantation rate was defined as number of ultrasonographically visualized gestational sacs per number of embryos transferred. Ongoing pregnancy was defined as a uterine pregnancy of more than 12 weeks' duration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409301556N64**

Registration date: **2014-10-11, 1393/07/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-11, 1393/07/19

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, 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

2014-10-12, 1393/07/20

Expected recruitment end date

2016-12-01, 1395/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on the pregnancy outcomes of IVF between GnRH-a and OCP in women with moderate and

sever endometriosis.

Public title

Effect of GnRH-a and OCP on the result of IVF in females with moderate and sever endometriosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Hundred infertile women with moderate and sever endometriosis according to the revised American Fertility Society classification were scheduled for IVF. These patients were in line with: moderate and sever endometriosis; age less than 35 years old; FSH level below 10 U/L; 27>BMI>20. Exclusion criteria: minimal and mild endometriosis; potentially poor responder; endocrine disorders.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size:

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

Tehran University of Medical Sciences, Ghods Avn., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2003-05-27, 1382/03/06

Ethics committee reference number

/130/514/93/

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Noninflammatory disorders of female genital tract

Primary outcomes

1

Description

Number of retrieved oocytes

Timepoint

Oocyte retrieval 34 to 36 hours after the hCG injection

Method of measurement

Base on microscopic finding

2

Description

Number of MII oocytes

Timepoint

MI oocytes after retrieval

Method of measurement

Base on microscopic finding

3

Description

Fertilization rate

Timepoint

Fertilization was assessed by pronuclei formation at 24 h after oocyte retrieval and by subsequent cleavage

Method of measurement

Base on microscopic finding

4

Description

Implantation rate

Timepoint

Implantation rate was defined as number of ultrasonographically visualized gestational sacs

Method of measurement

Ultrasonography

5

Description

The number of embryo transfer

Timepoint

Day 2 or day 3 embryos were transferred

Method of measurement

patient's file

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

Ongoing pregnancy was defined as a uterine pregnancy of more than 12 weeks' duration

Method of measurement

Ultrasonography

2

Description

pregnancy rate per embryo transfer

Timepoint

pregnancy rate was defined as number of ultrasonographically visualized gestational sacs per number of embryos transferred

Method of measurement

ultrasonography

Intervention groups

1

Description

Hundred infertile women with mod and sever endometriosis according to the revised American Fertility Society classification were scheduled for IVF. In interventional group(50) the patients takes OCP for 6-8 Weeks before IVF then received a standard controlled ovarian hyperstimulation (COH) regimen. It consisted of subcutaneous injections of 0.05 to 0.1 mg/day of a GnRH agonist (Diphereline 0.1 mg) for 7 to 10 days in the mid-luteal phase for pituitary down-regulation, and exogenous ovarian stimulation with gonadotropin was initiated on the second or third day after the onset of menstruation . Human chorionic gonadotropin (hCG) was administered to trigger egg maturation when at least 1 follicle achieved a mean diameter of 17 mm. The patients were scheduled for oocyte retrieval 34 to 36 hours after the hCG injection. Indications and techniques for oocyte aspiration, oocyte and embryo culture, insemination, intracytoplasmic sperm injection,, and embryo transfer were based on the routine of the center. Embryos were transferred at the 4- or 8- cell stage. Response to controlled ovarian hyperstimulation and IVF-ET cycle outcome were compared between groups. Clinical pregnancy was defined as an elevated serum hCG and the presence of a gestational sac on transvaginal ultrasound. Implantation rate was defined as number of ultrasonographically visualized gestational sacs per number of embryos transferred. Ongoing pregnancy was defined as a uterine pregnancy of more than 12 weeks' duration.

Category

Treatment - Drugs

2

Description

Hundred infertile women with mod and sever endometriosis according to the revised American Fertility Society classification were scheduled for IVF . In control group(50) the patients received a 3.75-mg intramuscular injection of a GnRH agonist (Diphereline) twice, at a 28 days' interval. Controlled ovarian hyperstimulation was initiated within 10 days of the last GnRH agonist injection. Ovarian stimulation was achieved using FSH (Gonal-F;) and/or human menopausal gonadotropin . Human chorionic gonadotropin (hCG) was administered to trigger egg maturation when at least 1 follicle achieved a mean diameter of 17 mm. The patients were scheduled for oocyte retrieval 34 to 36 hours after the hCG injection. Indications and techniques for oocyte aspiration, oocyte and embryo culture, insemination, intracytoplasmic sperm injection,, and embryo transfer were based on the routine of the center. Embryos were transferred at the 4- or 8- cell stage. Response to controlled ovarian hyperstimulation and IVF-ET cycle outcome were compared between groups. Clinical pregnancy was defined as an elevated serum hCG and the presence of a gestational sac on transvaginal ultrasound. Implantation rate was defined as number of ultrasonographically visualized gestational sacs per number of embryos transferred. Ongoing pregnancy was defined as a uterine pregnancy of more than 12 weeks' duration

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

Mahboobeh Mohammadi

Street address

Arash Hospital, Rashid Ave, Tehranpars, Resalat Highway,Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Massod Yunesian

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Tehran University of Medical Sciences, Ghods Avn., Keshavarz Blvd.,Tehran

City

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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
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
Arash Hospital

Full name of responsible person
Mahboobeh Mohammadi

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Person responsible for scientific inquiries

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Person responsible for updating data

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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