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 endomethriosis.

Public title
Effect of GnRH-a and OCP on the result of IVF in females with moderate and sever endomethriosis.
Purpose
Treatment
Inclusion/Exclusion criteria
Hundred infertile women with moderate and sever endomethriosis 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; potentialy 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/د

Health conditions studied

1

Description of health condition studied
Endomethriosis
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
MII 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
pationt'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 endomethriosis 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 endomethriosis 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
Street address
Tehran University of Medical Sciences, Ghods Avn., Keshavarz Blvd.,Tehran
City
Tehran

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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Other areas of specialty/work
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Fax
Email
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arash Hospital
Full name of responsible person
Dr. Ladan Kashani
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Endocrinology and infertility fellowship
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Fax
Email
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arash Hospital
Full name of responsible person
MahboobeH Mohammadi
Position
Gynecology assistant
Other areas of specialty/work
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Arash Hospital, Rashid Ave, Tehranpars, Resalat Highway,Tehran
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Fax
Email
maha0058@yahoo.com
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