Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of the effect of pretreatment of E2 and OCP before Antagonist cycle on IVF outcome.

Protocol summary

Summary

Worldwide, gonadotrophin-releasing hormone (GnRH) antagonists are gaining ground, and. During the past 2 years, debate has been ongoing about the possible disadvantages of oral contraceptive pill (OCP) pre-treatment in GnRH antagonist IVF cycles. Therefore, this study aimed the whether or not OCP pre-treatment might have effect on outcome in GnRH antagonist IVF cycles. This is single blind Clinical Trial study and will be done on 195 patients that candidate to IVF from winter 1395 to spring the year of 1396 in infertility center of Imam Khomeini hospital patients with inclusion criteria (women with 20-35 years old; without any pathology in ovary or endometrioma, myoma or any hydrosalpinx) are divided randomly to 3 groups. In group 1 (65 patients) only antagonist 25 miligram daily is administrated from the second day of the cycle. In group 2 (65 patients), daily treatment is a pill (OCP) for 10 days and 10-12 days before the last cycle. In group 3, daily treatment is a Estradiol Pill for 10 days and before the start of antagonist administration. In all three groups of patients after 6 days of treatment, vaginal ultrasound will be done every other day. When the follicles greater than 13 mm was observed, antagonist starts with 25 mg and when there is at least three follicles greater than 17 mm, HCG 10000 unit is injected. After 36 hours, pick up the ovum will be done. In all three groups, the number of oocyte, days of stimulation as a primary outcomes and chemical and clinical pregnancy rates will be considered as a secondary outcome.This is single blind study that analyzer is blinded for the 3 treatment groups.

General information

Acronym

OCP; E2; Antagonist

IRCT registration information

IRCT registration number: **IRCT2017020520351N9**

Registration date: **2017-02-21, 1395/12/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-21, 1395/12/03

Registrant information

Name

Ensieh Shahrogh Tehraninejad

Name of organization / entity

Tehran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1616

Email address

etehraninejad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Science.

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of pretreatment of E2 and OCP before Antagonist cycle on IVF outcome.

Public title

Evaluation of the effect of pretreatment of E2 and OCP in Antagonist cycle In IVF cycles.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with 20-35 years old; prior IVF less than 2; AFC>4; FSH<10; without any pathology in ovary or endometrioma more than 1cm; without any hydrosalpinx. Exclusion criteria: PCOS; pathology in uterus or ovary (myoma larger than 5 cm); absence of vaginal bleeding until 6 days after disconnection of OCP or E2; lack of permission of patients.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **195**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Central Building, Tehran University of Medical Sciences, Ghods Street,

City

Tehran

Postal code

14194

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

92345

Health conditions studied

1

Description of health condition studied

Female infertility associated with anovulation

ICD-10 code

N97.0

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Oocyte number

Timepoint

Six days after treatment

Method of measurement

Vaginal sonography

2

Description

Number of induction ovulation

Timepoint

After treatment

Method of measurement

Transvaginal sonography

Secondary outcomes

1

Description

Chemical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

B-HCG Test

2

Description

Clinical pregnancy

Timepoint

Three weeks after do positive of pregnancy teset

Method of measurement

Transvaginal sonography

Intervention groups

1

Description

In group without intervention (Control): only antagonist 25 miligram daily is administrated from the second day of the cycle. In all three groups of patients after 6 days of treatment, vaginal ultrasound will be done every other day. When the follicles greater than 13 mm was observed, antagonist starts with 25 mg and when there is at least three follicles greater than 17 mm, HCG 10000 unit is injected. After 36 hours, pick up the ovum will be

done.

Category

Treatment - Drugs

2

Description

In intervention group 1: daily treatment is a pill (OCP) for 10 days and 10-12 days before the last cycle. In all three groups of patients after 6 days of treatment, vaginal ultrasound will be done every other day. When the follicles greater than 13 mm was observed, antagonist starts with 25 mg and when there is at least three follicles greater than 17 mm, HCG 10000 unit is injected. After 36 hours, pick up the ovum will be done.

Category

Treatment - Drugs

3

Description

In intervention group 2: daily treatment is a Estradiol Pill for 10 days and before the start of Antagonist administration. In all three groups of patients after 6 days of treatment, vaginal ultrasound will be done every other day. When the follicles greater than 13 mm was observed, antagonist starts with 25 mg and when there is at least three follicles greater than 17 mm, HCG 10000 unit is injected. After 36 hours, pick up the ovum will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Infertility Clinic

Full name of responsible person

Dr. Fatemeh Bakhtiari

Street address

Valiasr Infertility Clinic, Imam Khomeini Hospital, Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Floor N.6, Central Bulding,Tehran University of Medical Sciences, Ghods Street.

City

Tehran

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

Reproductive Health Research Center

Full name of responsible person

Fatemeh Bakhtiari

Position

Infertility Flowship

Other areas of specialty/work

Street address

First floor, Valiasr Hospital 2, Imam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Postal code

14194

Phone

+98 21 6658 1658

Fax

Email

bakhtiyari1355@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Reproductive Health Research Center

Full name of responsible person

Farnaz Sohrabvand

Position

Professor

Other areas of specialty/work

Street address

First floor, Valiasr Hospital 2, Imam Khomeini Hospital, Keshavarz Blvd.

City

Tehran

Postal code

14194
Phone
+98 21 6658 1658
Fax
+98 21 6658 1658
Email
fsohrabvand@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Vali Asr Reproductive Health Research Center
Full name of responsible person
Fedyeh Haghollahi
Position
Expert in Research
Other areas of specialty/work
Street address
First floor, Valiasr Hospital 2, Imam Khomeini Hospital, Keshavarz Blvd.
City
Tehran
Postal code
14194
Phone
+98 21 6658 1658
Fax
+98 21 6658 1658
Email
fedyeh_hagh@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