Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Luteal phase estradiol versus luteal phase GnRH antagonist administration: their effects on antral follicular size coordination and basal hormonal levels

Protocol summary

Summary

The aim of this study is to compare the previous luteal phase administration of Estradiol and GnRH antagonist on follicular size coordination and hormones level in ICSI cycle, antagonist protocol. Thirty 20-35 years old women, with male factor infertility who are candidate for IVF with regular menstrual cycles and normal Body mass index (BMI) will be recruited. Exclusion criteria are those with history of hormone therapy for the past preceding 3 months or single ovary . All women, on 3th day of first cycle, undergo the transvaginal ultrasonography to measure the size and number of antral follicles. Serum level of FSH ,Inhibin and Estradiol will measure. Then they will allocate to two groups. In first group, from 20th day, estradiol tab 4 mg daily will administer until next 2nd day of cycle. In other group, single dose of GnRH antagonist (Amp cetrotide) will inject on 25th cycle day. In 3rd day of next cycle, sonography and level of serum hormone will be evaluated. Primary out comes are coordination of follicle size and hormone levels before and after the intervention.Exclusion criteria are those with history of hormone therapy for the past preceding 3 months or single ovary . In all women on day 3 of first cycle the transvaginal ultrasonography to measure the size and number of antral follicles is done and the serum level of FSH ,Inhibin and Estradiol is evaluated then they in luteal phase are randomized to two group ,in group 1 on cycle day 20 estradiol tab 4 mg daily orally is administered until cycle day 2 of next cycle and in group 2 GNRH antagonist Amp cetrotide single dose is infused on cycle day25 then in two group on cycle day 3 of next cycle the sonography and serum hormone evaluation is repeated such as day 3 of previous cycle .Primery out come are coordination of follicle size and hormone levels before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103052568N2**
Registration date: **2011-05-03, 1390/02/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-05-03, 1390/02/13

Registrant information

Name

Haleh Rahmanpour

Name of organization / entity

Zanjan university of medical science

Country

Iran (Islamic Republic of)

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+98 241413003

Email address

haleh509@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Luteal phase estradiol versus luteal phase GnRH antagonist administration: their effects on antral follicular size coordination and basal hormonal levels

Public title
Comparison of two interventions on IVF outcome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria : 20-35 years old , male factor infertility , candidate for IVF , regular menstrual cycles , normal Body mass index (BMI) . Exclusion criteria :Those with history of hormone therapy for the past preceding 3 months , single ovary .
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: **30**
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
Tehran University of Medical Sciences
Street address
Keshavarz Blvd - Ghods street
City
Tehran
Postal code
Approval date
2008-04-20, 1387/02/01
Ethics committee reference number
798

Health conditions studied

1

Description of health condition studied
complications associated with artificial fertilization
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
size of antral follicles
Timepoint
20 days before intervention and 10 days after intervention
Method of measurement
transvaginal sonography

Secondary outcomes

1

Description
serum FSH
Timepoint
20 days before intervention and 10 days after intervention
Method of measurement
blood sample

2

Description
Serum inhibin
Timepoint
20 dayes before intervention and 10 dayes after intervention
Method of measurement
blood sample

3

Description
Serum Estradiol
Timepoint
20 days before intervention and 10 days after intervention
Method of measurement
Blood sample

Intervention groups

1

Description
In intervention group one GNRH antagonist ampule is

infused subcutaneusly on 25th of first cycle .

Category

Treatment - Drugs

2

Description

in control group 4 mg Estradiol tab daily administered from 20th day of first cycle to 2nd day of second cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Haleh Rahmanpour

Street address

Keshavarz Blvd,Emam Khomeini hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fedieh Haghollahi

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Valiasr hospital

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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

Thran University of Medical Sciences

Full name of responsible person

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Position

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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