Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparison the effect of Gonadotropin releasing hormone agonist administration versus vaginal Progesterone on serum progesterone in luteal phase in ovarian hyperstimulation and intrauterine insemination cycles in unexplained infertility

Protocol summary

Summary

This study is a prospective randomize controlled trial study. In this study we will compare the effect of Gonadotropin releasing hormone agonist administration versus vaginal Progesterone on serum progesterone in luteal phase in ovarian hyperstimulation and intrauterine insemination cycles in unexplained infertility. 242 patients (unexplained infertility reffered to the infertility Center of Mirza khochak khan Hospital) according to inclusion criteria (age<40 years old; FSH<10; normal Serum prolactin and thyroid function test; duration of infertility at least 1 year for each case; Normal hysterosalpigography in 6 month ago; normal semen analysis with WHO criteria (20 million sperm inml, 50%motility, 30% normal morphology); Regular menstruation cycles with midluteal progesterone>10ng/ml in previous cycles) and exclusion criteria (previous ovarian surgery; Single ovary; polycystic ovaries on ultrasound examination; hypogonadotropic hypogonadism) will be selected. In all patients, transvaginal ultrasonography will be performed on 3rd day of the menstrual cycle and then will be stimulated with dose of 100mg Clomiphene from 3rd day to 7th day menstrual cycles.Then administration of Gonadotropin (75IU IM)will begin from 7th and 8th day cycle .Ovarian response will be assesed with trans vaginal sonography from 10th day of each cycle. Cycles will trigger with 10000 IU HCG when at least one dominant follicle has reach 18 mm in diameter.The intrauteine insemination will be performed 36 hrs after HCG administration with a intra uteine insemination disposable catheter.Then all cycles will be divided in 2 group. In first group, luteal phase will be supported with vaginal progesterone 400mg daily ,1 days after insemination until 14 days.The second group will receive a single subcutaneous injection of 0.1 mg GNRH Agonist(triptoreline) 4 days after intra uteine insemination. Serum progesterone will be measured 10 days after intra uteine insemination .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205159762N1**
Registration date: **2012-07-11, 1391/04/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-07-11, 1391/04/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2012-06-09, 1391/03/20

Expected recruitment end date
2012-08-22, 1391/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of Gonadotropin releasing hormone agonist administration versus vaginal Progesterone on serum progesterone in luteal phase in ovarian hyperstimulation and intrauterine insemination cycles in unexplained infertility

Public title
Comparison the effect of Gonadotropin releasing hormone agonist administration versus vaginal Progesterone on serum progesterone in luteal phase in ovarian hyperstimulation and intrauterine insemination cycles in unexplained infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age<40 years old; FSH<10; normal Serum prolactin and thyroid function test; duration of infertility at least 1 year for each case; Normal hysterosalpigography in 6 month ago; normal semen analysis with WHO criteria (20 million sperm inml, 50%motility, 30% normal morphology); Regular menstruation cycles with midluteal progesterone>10ng/ml in previous cycles exclusion criteria: previous ovarian surgery; Single ovary; polycystic ovaries on ultrasound examination; hypogonadotropic hypogonadism
Age
From **17 years** old to **39 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **242**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee o fVice-Chancellor for research of Tehran University of Medical Sciences
Street address
Vice-Chancellor for research of Tehran University of Medical Sciences,Ghods Avenve, Keshavarz Blvd, Tehran, Iran
City
Tehran
Postal code
Approval date
2012-06-09, 1391/03/20
Ethics committee reference number
91-02-39-18352

Health conditions studied

1

Description of health condition studied
infertility
ICD-10 code
n97.9
ICD-10 code description
female infertility,unspecified

Primary outcomes

1

Description
serum progesterone in luteal phase
Timepoint
10 days after intra uterine insemination
Method of measurement
blood sampling-ng/ml

Secondary outcomes

1

Description
pregnancy
Timepoint
14 days after intra uterine insemination
Method of measurement
blood sampling-iu/ml

Intervention groups

1

Description
Group1:Clomiphene 100mg daily from 3rd day to 7th day of the menstrual cycle,Gonadotopin(75 IU IM) injection 7th and 8th day , Human chorionic gonadotropin (10000

IU IM) will be administered when dominant follicle18 mm will measure,The intra uterine isemination will be performed 36 hrs after HCG administration, Vaginl progesterone (400 mg/day) begin from a day after intrauterine insemination to 14 days

Category

Treatment - Drugs

2

Description

Group2: Clomiphene 100mg daily from 3rd day to 7th day of the menstrual cycle,Gonadotopin(75 IU IM) injection 7th and 8th day , Human chorionic gonadotropin (10000 IU IM) will be administered when dominant follicle18 mm will measure,The intra uterine isemination will be performed 36 hrs after HCG administration,Triptoreline (0.1 mg Sc) injection 4 days after intrauterine insemination

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ivf Center Mirzakochakkhan Hospital

Full name of responsible person

Jaleh Mohamadpoor

Street address

Ivf Center Mirzakochakkhan Hospital,North Ostad nejatolahi, Karimkhan street, Tehran,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Miss Rahmani

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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 of 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

Tehran University of Medical Sciences

Full name of responsible person

Jaleh Mohamadpoor

Position

Gynecologist

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