Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Controlled trial of comparison of the effect of controlled ovarian stimulation protocols on gene expression of germinal vesicle oocytes in infertile women

Protocol summary

Summary

The objective of the present study is to compare the expression of genes in germinal vesicle oocyte between receiving the gonadotropin releasing hormone antagonist (GnRH-ant) and gonadotropin releasing hormone agonist (GnRH-a) long protocols in controlled ovarian stimulation of infertile women. Inclusion criteria include: age 18-40 years; normal serum level of steroidal hormones; male infertility, tubal factor infertility unexplained infertility. Exclusion criteria include: poly cystic ovarian; moderate or severe endometriosis and genetic disease. Fifty infertile women undergo controlled ovarian stimulation with either the GnRH-a long protocol or GnRH-ant fixed multi-dose protocol, randomly. One hundred morphologically healthy germinal vesicle (GV) oocytes donated by fifty infertile women will collect in the Infertility center of Tehran Women General Hospital, Tehran University of Medical Sciences, Iran. After the sampling, pools of fifty GV oocytes for each group will separately analyz by Real time PCR. Finally we will assess the expression levels of genes involved in the cytoplasmic maturity: growth and differential factor 9 (GDF9) and bone morphogenetic protein 15 (BMP15); antiapoptotic process: neuronal apoptosis inhibitory protein (NAIP), and adenosine triple phosphate 6 (ATPase 6) in human germinal vesicle oocytes in the GnRH-ant protocol group versus the GnRH-a long protocol group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031112307N3**
Registration date: **2014-04-21, 1393/02/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-21, 1393/02/01

Registrant information

Name

Fatemeh Sadat Hoseini

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-09-20, 1391/06/30

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Controlled trial of comparison of the effect of controlled ovarian stimulation protocols on gene expression of germinal vesicle oocytes in infertile women

Public title

Controlled trial of comparison of the effect of controlled ovarian stimulation protocols on gene expression of

germinal vesicle oocytes in infertile women

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria: age 18-40 years; normal serum level of steroidal hormones; male infertility, tubal factor infertility and unexplained infertility. Exclusion criteria: genetic diseases; moderate or severe endometriosis and poly cystic ovarian.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Vice chancellor for Research,Tehran University of Medical Sciences

Street address

Ghods St., Keshavarz Blvd., Teharn

City

Tehran

Postal code

1417653761

Approval date

2012-11-25, 1391/09/05

Ethics committee reference number

130/1743

Health conditions studied

1

Description of health condition studied

Contrlled Ovarian Stimulation protocols

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Determination of the effect of controlled ovarian stimulation protocols on gene expression of germinal vesicle oocytes in infertile women

Timepoint

End of sampling

Method of measurement

Real Time PCR

Secondary outcomes

1

Description

Determination of the effect of controlled ovarian stimulation protocols on adenosine triphosphatase 6 gene expression of human germinal vesicle oocytes

Timepoint

The end of sampling

Method of measurement

Real Time PCR

2

Description

Determination of the effect of controlled ovarian stimulation protocols on growth differentiation factor 9 gene expression of human germinal vesicle oocytes

Timepoint

The end of sampling

Method of measurement

Real Time PCR

3

Description

Determination of the effect of controlled ovarian stimulation protocols on bone morphogenetic protein15 gene expression of human germinal vesicle oocytes

Timepoint

The end of sampling

Method of measurement

Real Time PCR

4

Description

Determination of the effect of controlled ovarian stimulation protocols on neuronal apoptosis inhibitory protein gene expression of human germinal vesicle oocytes

Timepoint

The end of sampling

Method of measurement

Real Time PCR

Intervention groups

1

Description

Control group: In the gonadotropin releasing hormone agonist long protocol group, the administration of Buserelin acetate 500 µg/d is started subcutaneously proceeding the IVF cycle from day 21 until pituitary down regulation. The Buserelin dose is reduced to 250 µg/d until the day of human chorionic gonadotropin (hCG) injection when pituitary down regulation was achieved. Ovarian stimulation is started on the 3rd day of the current menstrual cycle by injection of rFSH Follitropin alfa (Gonal F) at a daily dose of 150 to 225 IU/IM. Human chorionic gonadotropin 5000 IU /2/IM is injected about 34–36 hrs before oocytes pickup day.

Category

Treatment - Drugs

2

Description

Intervention group: In the gonadotropin releasing hormone antagonist fixed multi-dose protocol group, Cetrorelix acetate 0.25 mg/day subcutaneously is initiated on the sixth day of the gonadotropin stimulation until the day of hCG injection. Ovarian stimulation is started on the 3rd day of the current menstrual cycle by injection of rFSH Follitropin alfa (Gonal F) at a daily dose of 150 to 225 IU/IM until the day of human chorionic gonadotropin injection. Human chorionic gonadotropin 5000 IU /2/IM is injected about 34–36 hrs before oocytes pickup day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Women General Hospital

Full name of responsible person

Nasser Salsabili

Street address

North Negatollahi St., Karim Khan St., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotohi

Street address

Ghods St., 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyed Mohammad Hossein Noori Mugahi

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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