Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Compare the efficacy of two protocols of ovarian stimulation using Gonal-F and Luveris in women with hypogonadotropic hypogonadism undergoing assisted reproductive technique Compare the efficacy of two protocols of ovarian stimulation using Gonal-F and Luveris in women with hypogonadotropic hypogonadism undergoing assisted reproductive technique

Protocol summary

Summary

This study compares the efficacy of two protocols of ovarian stimulation using Gonal-F and Luveris in women with hypogonadotropic hypogonadism undergoing assisted reproductive technique. In this single blind randomized clinical trial, women with a clinical history of hypogonadotrophic hypogonadism who stopped any treatment with gonadotrophins >1 month before study, with a negative progesterone challenge test, low serum gonadotrophins (LH and FSH less than 5.0 IU/l) and oestradiol (less than 100 pg/ml) and normal serum concentrations of thyroid stimulating hormone (TSH), testosterone and prolactin within 6 months before the start of treatment are enrolled. Other causes of infertility are excluded from the study. In this study 90 infertile women with hypothalamic amenorrhea undergoing assisted reproductive technique in the Royan Institute are studied. All patients receive treatment with Gonal-F (rFSH) (starting dose 150 IU/day and from day 2-3 according to the ovarian response) and Luveris (rLH) (fixed dose of 75 IU/day). When at least one follicle reaches 14 mm in diameter, 4mg/day oestradiol is administered and patients are randomly divided into two groups: Luveris alone (intervention group) and continued treatment with both drugs Gonal-F and Luveris (control group). At the end, the number and size of ovarian follicles, endometrial thickness on the day of injection of hCG and the number of oocytes retrieved will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312251141N16**
Registration date: **2015-02-12, 1393/11/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-12, 1393/11/23

Registrant information

Name
Kiandokht Kiani
Name of organization / entity
Royan Institute
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2012-11-13, 1391/08/23

Expected recruitment end date

2015-12-27, 1394/10/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Compare the efficacy of two protocols of ovarian stimulation using Gonal-F and Luveris in women with hypogonadotropic hypogonadism undergoing assisted reproductive technique Compare the efficacy of two protocols of ovarian stimulation using Gonal-F and Luveris in women with hypogonadotropic hypogonadism undergoing assisted reproductive technique

Public title
Comparison of ART Outcomes between Two Protocols of Induction of ovulation in Patients with Hypogonadotropic Hypogonadism

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Have a clinical history of hypogonadotropic hypogonadism, and laboratory test result comply with diagnosis of hypogonadotropic hypogonadism; Have discontinued gonadotropins or gonadotropin releasing hormone or estrogen-progesterone replacement therapy at least one month before the study; Have primary or secondary amenorrhea; Serum LH and FSH <5.0 IU/l and oestradiol <100 pg/ml before initiation of treatment; Have a negative progesterone challenge test; Normal serum concentrations of thyroid stimulating hormone (TSH), prolactin and testosterone within 6 months before the start of study; Have given written informed consent prior to any study related procedure Exclusion Criteria: The other causes of infertility; History of ovarian hyper stimulation syndrome; Abnormal gynecological bleeding of undetermined origin; Previous or current hormone dependent tumor

Age
No age limit

Gender
Female

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **90**

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
Royan Institute.rg

Street address
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City
tehran

Postal code

Approval date
2012-09-25, 1391/07/04

Ethics committee reference number
EC/91/1089

Health conditions studied

1

Description of health condition studied
• Female infertility associated with anovulation

ICD-10 code
E23.0

ICD-10 code description
Hypopituitarism

Primary outcomes

1

Description
The number and size of follicles

Timepoint
Before injection of hCG

Method of measurement
Sonography

2

Description
Endometrial thickness

Timepoint
Day of injection of hCG

Method of measurement
Sonography

3

Description
The number of oocytes retrieved

Timepoint
34-36 hours after hCG injection

Method of measurement
Sonography

Secondary outcomes

1

Description
Fertilization
Timepoint
2-3 days before the embryo transfer
Method of measurement
observation of 2 pro-nuclei (2PN)

2

Description
Biochemical pregnancy
Timepoint
2 weeks after embryo transfer
Method of measurement
BhCG test

3

Description
Clinical pregnancy
Timepoint
4-6 weeks after embryo transfer
Method of measurement
Ultrasound visualization of a gestational sac

4

Description
Implantation
Timepoint
4-6 weeks after embryo transfer
Method of measurement
Number of gestational sacs by Sonography

Intervention groups

1

Description
Intervention: Patients receive treatment with Gonal-F (starting dose 150 IU subcutaneously once daily and from day 2-3 according to the ovarian response) and Luveris (fixed dose of 75 IU subcutaneously once daily). When at least one follicle reaches 14 mm in diameter, intervention group continue Luveris alone.
Category
Treatment - Drugs

2

Description
Control: Patients receive treatment with Gonal-F (starting dose 150 IU subcutaneously once daily and from day 2-3 according to the ovarian response) and Luveris (fixed dose of 75 IU subcutaneously once daily). When at least one follicle reaches 14 mm in diameter, control group continue treatment with both drugs (Gonal-F/Luveris).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Tahereh Madani
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Royan Institute
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

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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