Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of low-dose hCG adjunct to r-hFSH plus GnRH antagonist for ovarian stimulation in assisted reproductive technology

Protocol summary

Summary

The aim of this study is to evaluate the effect of adding low-dose hCG to GnRH antagonist+r-hFSH protocole on the outcome of ART in the patients undergoing IVF/ICSI cycle. This study is a clinical trial. In all 120 patients pre-treatment with OCP will be given during the cycle prior to the IVF/ICSI. r-hFSH (150-300 IU) will be loaded on either day 2 or 3 of the menstural cycle, and the full dose will be continued until two follicles reach 14-15 mm in size, then daily administration of 0.25 mg of cetrorelix will be started. The starting dose of FSH will be chosen according to patient's age, BMI, and ovarian responsiveness in previous cycle. according to the study group, patients will receive or will not, a daily injection of hCG (200 IU). when at least 2 follicles reach 18 mm in size, 10000 IU of hCG will be injected and oocyt retrieval will be performed within 35-36 hours. After that, All patients will undergo an ICSI procedure. Luteal phase will be started on the day of oocyt retrieval by vaginal administration of cyclogest 400 mg/day. BhCG will be checked 15 days after oocyte retrieval and pregnancy will be confirmed by pregnancy sac visualization by week 6. Serum E2 level on the day of hCG administration, number of total oocyts, number of mature oocyt, FSH total dose, duration of stimulation, number of good quality embryo, fertilization and pregnancy rate will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211197165N2**
Registration date: **2012-11-25, 1391/09/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-25, 1391/09/05

Registrant information

Name
Ladan Kashani
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8828 1866
Email address
kashani_ladan@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-02-21, 1391/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of low-dose hCG adjunct to r-hFSH plus GnRH antagonist for ovarian stimulation in assisted reproductive technology

Public title

Efficacy of low-dose hCG adjunct to r-hFSH plus GnRH antagonist for ovarian stimulation in assisted reproductive technology

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: infertile female patient; age between 20-39 years old; body mass index(BMI) of 20- 25 kg/m2; a normal uterus and two functional ovaries; day 3 FSH level< 10 IU/L and E2 level< 60 pg/ml.Exclusion criteria: history of > 2 unsuccessful IVF/ICSI attempts; poor ovarian response in previous IVF/ICSI treatment and any endocrine disorders.

Age

From **20 years** old to **39 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Ethic Committee of Tehran University of Medical Sciences

Street address

Ethic Committee of Tehran University of Medical Sciences, 16 azar avenue, Keshavarz bolvar

City

Tehran

Postal code

Approval date

2007-04-25, 1386/02/05

Ethics committee reference number

5739

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Beta-hCG level

Timepoint

15 days after oocyte retrieval

Method of measurement

By laboratory kit from blood sample

Secondary outcomes

1

Description

Number of mature oocytes

Timepoint

35-36 hours after high-dose hCG injection

Method of measurement

Transabdominal ultrasound

Intervention groups

1

Description

r-hFSH + GnRH antagonist

Category

Treatment - Drugs

2

Description

r-hFSH + GnRH antagonist + low-dose hCG

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

Dr. Ladan Kashani

Street address

Tehran Pars, Rashid Street, Arash Hospital

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. Akbar Foutohi
Street address
Tehran University of Medical Sciences, Keshavarz Blvd
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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ladan Kashani
Position
Assistant Prof.
Other areas of specialty/work
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Postal code
Phone
+98 21 7788 3195
Fax
Email
Kashani_ladan@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ladan Kashani
Position
Assistant Prof.
Other areas of specialty/work
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Postal code
Phone
+98 21 7788 3195
Fax
Email
kashani_ladan@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ladan Kashani
Position
Assistant Prof.
Other areas of specialty/work
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Postal code
Phone
+98 21 7788 3195
Fax
Email
kashani_ladan@tums.ac.ir
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