Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Comparison of two methods of dual- trigger and HCG-trigger on final oocyte maturation in infertile patients with ovarian normal response

Protocol summary

Summary

the aim of this study :evaluation of dual-trigger effect on oocyte quality in comparison with HCG-trigger study design:Randomized Controledl Trial,two centers,prospective,on infertile women ages between 18-40,with normal ovarian response, Inclusion criteria:regular mense;BMI=18-35;FSH days3<10 Exclusion criteria:FSH days 3>=10;AMH=<1.1; expectancy for ovarian hyper response;endocrine deases(DM ,..);uterine anomaly in HSG or hysteroscopy;sever male factor;history of OHSS;criteria of ovarian hyper response or ovarian poor response sample size:126 infertile women Intervention: in IVF cycle for final oocyte maturation routinely used of 10000 IU HCG(in our study in control group patient will receive this dosage of drug) ,in intervention group we will use of 5000 IU HCG with 0.2 mg decapeptyl(GNRH -agonist) this intervention will be done on the day of HCG trigger our goals:evaluation of this intervention on total oocyte number ,number of oocyte Metaphase II ,total number of embryos ,pregnancy rate ,rate of OHSS

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061722795N1**
Registration date: **2016-02-01, 1394/11/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Marzieh Ghasemi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5581

Email address

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Recruitment status

Recruitment complete

Funding source

we don`t need to funding source

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of dual- trigger and HCG-trigger on final oocyte maturation in infertile patients with ovarian normal response

Public title

Comparison of dualL-Trigger and hcg-Trigger on infertile patients with normal ovarian response

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age18-40 years;regular mense(25-34 days);BMI between 18-35;FSH days 3 <10 exclusion criteria: FSH days 3 >=10;AMH=<1.1;expectancy for ovarian hyper response(>=16 follicles on the last trans vaginal sonography);endocrine deases(DM ,hyperprolactinemia,thyroide dysfunction ,CAH,cushing

syndrome);PCOs;uterine anomaly in HSG or hysteroscopy;sever male factor(azospermia require to TESE or PESA);history of OHSS;criteria of ovarian hyper response or ovarian poor response

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: **126**

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
Tehran University of Medical Sciences

Street address
central building of Tehran University of Medical Sciences ,keshavarz BLV,Tehran,Iran

City
Tehran

Postal code
1417614411

Approval date
2016-01-06, 1394/10/16

Ethics committee reference number
IR.TUMS.REC.1394.1578

Health conditions studied

1

Description of health condition studied
infertility

ICD-10 code
N97.0,N97.

ICD-10 code description
Female infertility associated with anovulation,Female infertility of tubal origin,Female infertility associated with male factors,Female infertility of other origin,Female infertility, unspecified,

Primary outcomes

1

Description
Number of Metaphase II oocyte

Timepoint
on oocyte retrieval day

Method of measurement
evaluation by embryologist under microscope

2

Description
number of Metaphase II oocytse ,total number of oocytes,number of embryoss

Timepoint
oocyte retrieval day,day3 after oocyte retrieval or IVF

Method of measurement
evaluation under microscope by an embryologist and scoring by scientific evidence

Secondary outcomes

1

Description
biochemical pregnancy ,clinical pregnancy,abortion ,OHSS

Timepoint
two weeks after transfer for biochemical pregnancy,4weeks for clinical pregnancy,2 weeks after transfer for OHSS

Method of measurement
BHCG for biochemical ,trans vaginal sonography for clinical,clinical evaluation for OHSS

Intervention groups

1

Description
In the intervention group for final oocyte maturation use of 5000 IU HCG intramuscular with 0.2 mg subcutaneous Decapeptyl(GNRH-agonist)

Category
Treatment - Drugs

2

Description
In the control group patients receive 10000IU HCG for final oocyte maturation

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
OMID Infertility Clinic

Full name of responsible person
Dr Ashraf Alyacine ,infertility fellowship ,professor of obestetrics and gynecology in Tehran Univer

Street address
No. 87, next to the Embassy of Romania, Shahid Meshki street(FAKHRABAD),Baharestan Street,Darvazehshemiran Streeet,Tehran,Iran

City
Tehran

2

Recruitment center

Name of recruitment center
Shriati hospital,Infertility ward

Full name of responsible person
Dr Marzieh Ghasemi,fellowship of infertility

Street address
Shariati hospital,Jalal-Al -Ahmad intersection kargar shomali,Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Ashraf Alyacin

Street address
Tehran, Keshavarz Blvd, Tehran University of Medical Sciences

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,infertility ward

Full name of responsible person
Marzieh Ghasemi

Position
fellowship in infertility

Other areas of specialty/work

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Shariati Hospital , Jalal-Al-Ahmad BLV intersection Kargar shomali,Tehran, Iran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences,Obestetrics and Gynecology group ,infertility ward

Full name of responsible person
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Position
professor of Obestetrics and Gynecology

Other areas of specialty/work

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Person responsible for updating data

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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