

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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+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 oocyte ,total number of oocytes,number of embryo

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 obstetrics and gynecology in Tehran Univer

Street address

No. 87, next to the Embassy of Romania, Shahid Meshki street(FAKHRABAD),Baharestan Street,Darvazeshemiran 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-AI -Ahmad intersection kargar shomali,Tehran

City

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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

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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**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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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