

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effect of recombinant HCG administration in follicular phase on clinical pregnancy rate in frozen cycles of infertile women.(Tehran,Omid infertility center,2014-2015

Protocol summary

Summary

Objectives: Assessment of recombinant HCG hormone in follicular phase on clinical fertility rate among freeze cycles of 250 infertile women of the study clinic. Design: randomized clinical trial with parallel design with two arms (intervention and control groups) Setting and conduct: All patients undergo long protocol cycle get contraceptive drugs and Folic Acid (five mg) from the third to 21th day of their cycle and then 0.5 mg Superfact (Sinafact) will be injected which will be continued up to the third day of the next period. According to Ultrasound study if the Endometrial thickness will less than three mm and without ovarian cyst, the amount of Superfact will be halved and one Estradiol tablet (two mg) for four days, two Estradiol Tablets (four mg) for next four days and then three Estradiol tablets after that (6mg) will be added. 125 units Recombinant HCG as trial intervention will inject for interventional group subcutaneously from 8th day of their period for seven days. In days 12th to 14th of the cycle, ultrasound will be done for all patients and if the thickness of Endometrium was between 8 to 14 mm, Progesterone Suppository (400u/bid) will prescribe and the Estradiol Tablets will be continued. After five days, the multicellular embryo (Blastocyst) will transfer. After two weeks if β HCG was positive two weeks later transvaginal ultrasound will be done, if FHR was detected estradiol will taper and progesterone suppository will continue until eight weeks. Clinical pregnancy among trial participants will determine as main outcome. Eligibility criteria: infertile women who were candidate for in vitro fertilization cycles and recipient of frozen embryo will include and women with uterus fibroma, polyps bigger than two centimeters or Mullerian anomaly will exclude. Intervention: Injection of 125 units Recombinant HCG subcutaneously from 8th day of their period for seven days. Main outcome measures: clinical

pregnancy rate according ultrasonography and fetal heart rate

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012020736N1**

Registration date: **2015-12-16, 1394/09/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-16, 1394/09/25

Registrant information

Name

Ashraf Alyasin

Name of organization / entity

Shariati hospital,Fertility center

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 8810

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of recombinant HCG administration in follicular phase on clinical pregnancy rate in frozen cycles of infertile women.(Tehran,Omid infertility center,2014-2015

Public title

Effect of recombinant HCG administration in infertile women with IVF procedure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women who were IVF candidate; infertile women who was recipient of Freezing embryo; Exclusion criteria: having uterus fibroma; having polyps bigger than 2 cm; Having Mullerian anomaly;

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 250

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Research Committee of Tehran University of Medical science

Street address

Medicine faculty, Poursina street, Tehran, Iran

City

Tehran

Postal code

1417613151

Approval date

2015-02-24, 1393/12/05

Ethics committee reference number

9111290027-129556

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N97

ICD-10 code description

Inability to achieve a pregnancy sterility

Primary outcomes**1****Description**

Chemical pregnancy

Timepoint

after four weekes

Method of measurement

B-HCG , miliunit

Secondary outcomes**1****Description**

Clinical pregnancy

Timepoint

two weeks after intervention

Method of measurement

transvaginal ultrasound and FHR

Intervention groups**1****Description**

for trial group|: 125 units Recombinant HCG will be injected Subcutaneously from 8th day of their period for 7 days of mensuration period. Daily injection of 25 mg progesterone and daily usage of 800 milligrams progesterone suppository

Category

Treatment - Drugs

2**Description**

Control group: Daily injection of progestron 25 mg and 800 milligrams progesterone suppository

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ifertility ward, Shariati Hospital

Full name of responsible person

Dr Ashraf Alyasin

Street address

Infertility ward, Shariati hospital, Kargar Shomali street, Jalal-e-Alahmad crossroad, Tehran, Iran

City

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2

Recruitment center

Name of recruitment center

Omid infertility center

Full name of responsible person

Dr Ashraf Alyasin

Street address

No 87, Near Romania embassy, Shahid Meshki Street, Baharestan Street, Darvazeh Shemiran Street, Tehran, Iran

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 Masoud Younesian

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Tehran University of Medical science, Keshavarz Blwd

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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

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 science

Full name of responsible person

Dr Mahshad Forati Kashani

Position

Ob&Gyn Resident

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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