

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparing pregnancy rate in GnRH agonist and letrozole plus gonadotropins protocol for endometrial preparation for frozen embryo transfer

Protocol summary

Summary

The purpose of this study is to compare the pregnancy rate in GnRH agonist protocol and letrozole plus gonadotropins protocol for endometrial preparation for frozen embryo transfer. Our main objective is pregnancy rate. The sample includes all women aged 18 to 42 years who undergoing endometrial preparation for frozen embryo transfer. Infertile couples with male infertility which undergo TESE or PESA, severe endometriosis (stage 3 or 4); uterine myoma with 4cm size or greater and fresh embryo transfer are excluded from the study. The sample includes 100 patients who are divided in two groups randomly. First group receives GnRH Agonist (Buserelin, Aventis, Germany) 500 µg subcutaneously from previous midluteal cycle (21th day). Then Estradiol valerat (Daroopaksh, Iran, 2 mg) daily oral is started on second day and is increased until the observation of 8mm endometrial thickness in transvaginal ultrasound. For visualizing endometrial thickness, Trans vaginal ultrasound (Sonoline G20; Siemens Medical Solutions, California, USA) is performed every 4 days. After the observation of at least 8mm endometrial thickness, Progesterone (Cyclogest, Germany, 800 mg) is started vaginally. After 3 days, Trans cervical embryo transfer will be carried out on day 16 to 19. Second group, receives letrozole (Iranhormone, Iran, 5mg daily) orally on 2th day of cycle for five days. Then HMG (Ferring, Germany, 75IU daily) is started on 7 day. After the observation of 18mm follicle in transvaginal ultrasound, HCG (Ferring, Germany, 10000IU, and IM) is injected for ovulation induction. Trans cervical embryo transfer is performed on day 16 to 19. Detection of chemical pregnancy is through serum BhCG analysis, 16 days after frozen embryo transfer and the clinical pregnancy is detected by the aid of trans vaginal ultrasound, two weeks later when the pregnancy sac is detected. Main outcome is chemical pregnancy rate. The rate of clinical

pregnancy and implantation are compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306256689N3**

Registration date: **2013-12-31, 1392/10/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-31, 1392/10/10

Registrant information

Name

Sedigheh Hosseinimousa

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 8800 8810

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2012-08-26, 1391/06/05

Expected recruitment end date

2013-12-26, 1392/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing pregnancy rate in GnRH agonist and letrozole plus gonadotropins protocol for endometrial preparation for frozen embryo transfer

Public title

Comparing two protocols for endometrial preparation for frozen embryo transfer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Infertile women 18-42 years old with freeze embryo Exclusion Criteria: 1- Male infertility which needs interventions such as TESE (Testicular Sperm Extraction) or PESA (Percutaneous Epididymal Sperm Aspiration) 2- Endometriosis (stage 3 or 4) 3- Uterine myoma with 4cm size or greater 4- Maternal age greater than 42 years old 5- Fresh embryo

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

All patients sign informed consents forms. The sample included 100 patients who are divided in two groups randomly based in Bernoli distribution.

Secondary Ids

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Ethics Committee, Tehran University of Medical

Sciences, Poorsina Street, Tehran

City

Tehran

Postal code

1417653761

Approval date

2012-05-22, 1391/03/02

Ethics committee reference number

90-04-30-15625-53627

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

Infertility

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male factors

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

Chemical Pregnancy

Timepoint

16 days after embryonal transfer

Method of measurement

βhCG titration

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

Clinical pregnancy

Timepoint

30 days after embryonal transfer

Method of measurement

Observed gestational sac in transvaginal sonography

2**Description**

Implantation Rate

Timepoint

30 days after embryonal transfer

Method of measurement

The number of observed gestational sac in transvaginal sonography / the number of transferred embryos * 100

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

First group receives GnRH Agonist (Bucerelin, Aventis, Germany) 500 µg subcutaneously from previous midluteal cycle (21th day). Then Estradiol valerat

(Daroopakshsh, Iran, 2 mg) daily oral is started on second day and is increased until the observation of 8mm endometrial thickness in transvaginal ultrasound. For visualizing endometrial thickness, Trans vaginal ultrasound (Sonoline G20; Siemens Medical Solutions, California, USA) is performed every 4 days. After the observation of at least 8mm endometrial thickness, Progesterone (Cyclogest, Germany, 800 mg) is started vaginally. After 3 days, Trans cervical embryo transfer will be carried out on day 16 to 19.

Category

Treatment - Drugs

2

Description

Second group, receives letrozole (Iranhormone, Iran, 5mg daily) orally on 2th day of cycle for five days. Then HMG (Ferring, Germany, 75IU daily) is started on 7 day. After the observation of 18mm follicle in transvaginal ultrasound, HCG (Ferring, Germany, 10000IU, and IM) is injected for ovulation induction. Trans cervical embryo transfer is performed on day 16 to 19.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Unit, Shariati Hospital

Full name of responsible person

Dr Sedighe Hoseinimosa

Street address

Department of Infertility, Shariati Hospital, Tehran University of Medical Sciences, North Karegar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masood Yunesian

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Vice Chancellor for Research, Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran

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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 Sciences, Shariati Hospital, Department of Infertility

Full name of responsible person

Dr Sedighe Hoseinimosa

Position

Infertility Fellowship

Other areas of specialty/work

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Position

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Other areas of specialty/work**Street address**

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Phone**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