# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jun 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 (Bucerelin, Aventis, Germany) 500 µg subcutaneously from previous midluteal cycle (21th day). Then Estradiol valerat (Daroopakhsh, 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**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8800 8810

**Email address**

hoseinimosa@sina.tums.ac.ir


**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

(Daroopakhsh, 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

**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 Masood Yunesian

**Street address**

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

**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, 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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## Person responsible for scientific inquiries

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Professor

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## Person responsible for updating data

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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*