

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Frozen embryo transfer: Randomized clinical trial on endometrial preparing by letrozole versus hormone replacement cycle

#### Protocol summary

##### Study aim

Comparing clinical outcome of letrozole versus hormone replacement for endometrial preparation in women with normal menstrual cycles for transferring frozen embryo .

##### Design

Randomized controlled trial

##### Settings and conduct

Patients in the infertility center of hazrat Zeynab Hospital will be undergo of: Intervention group: Administration of letrozole tab 5 mg from 3th day of menstrual cycle until the 7th day in the intervention group . Control group: administration of esteradiol from the 2th or 3th day of menstruation until the day 10th.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-42 years old women, having freeze embryos, normal uterine cavity, BMI <35 kg/m2.

Exclusion criteria: maternal underlying disease, hydrosalpinx,

##### Intervention groups

Intervention group: Administration of letrozole tab 5 mg from 3th day of menstrual cycle until the 7th day in the intervention group . Control group: administration of esteradiol from the 2th or 3th day of menstruation until the day 10th.

##### Main outcome variables

Clinical pregnancy rate, Chemical pregnancy rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190327043121N1**

Registration date: **2019-05-26, 1398/03/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-05-26, 1398/03/05**

Update count: **0**

##### Registration date

2019-05-26, 1398/03/05

##### Registrant information

###### Name

leila ghasempour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3233 2365

###### Email address

leilaghasempour97@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-05-26, 1398/03/05

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Frozen embryo transfer: Randomized clinical trial on endometrial preparing by letrozole versus hormone replacement cycle

##### Public title

letrozole versus hormone replacement cycle in endometrial preparing in embryo transfer

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

18-42 years old Freeze embryos Normal uterine cavity,

without any endometrial polyp or lesion. BMI <35 kg/m<sup>2</sup>

**Exclusion criteria:**  
Maternal underlying disease, Hydrosalpinx

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

**Gender**  
Female

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **167**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization: patients who have frozen embryo will be randomized based on the randomization table, after which is derived from [www.randomization.org](http://www.randomization.org).

**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

Ethics committee of Shiraz University of Medical Science

##### Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

#### Approval date

2018-07-29, 1397/05/07

#### Ethics committee reference number

IR.SUMS.REC.1397.406

## Health conditions studied

### 1

#### Description of health condition studied

infertility patients going ivf cycle with frozen embryo

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Clinical pregnancy rate

#### Timepoint

2 months after embryo transfer

#### Method of measurement

Ultrasonography

## Secondary outcomes

### 1

#### Description

Chemical pregnancy rate

#### Timepoint

14 days after transferring the embryo

#### Method of measurement

Pregnancy Test

## Intervention groups

### 1

#### Description

Intervention group: Administration of letrozole tab 5 mg from 3th day of menstrual cycle until the 7th day.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: administration of estradiol from the 2th or 3th day of menstruation until the day 10th.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hazrate Zeinab Hospital

##### Full name of responsible person

Leila Ghasempour Shirazi

##### Street address

Hazrate Zeinab Hospital, Defae moghadas square

##### City

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##### Province

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##### Postal code

7134544119

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**Email**

leilaghasempour97@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Younes Ghasemi

**Street address**

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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**Province**

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**Postal code**

71348 -44119

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**Fax**

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**Email**

sacrc@sums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Leila Ghasempour Shirazi

**Position**

Infertility fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Obstetrics department , Faghihi Hospital, Zand Street

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Alamtaj Samsami Dehaghani

**Position**

Infertility fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Leila Ghasempour Shirazi

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

hormonal data, ovarian stimulation data, embryo transfer data, pregnancy outcome

**When the data will become available and for how long**

6 month after acceptance of paper

**To whom data/document is available**

People who want to do work in this area and have scientific documentation can

**Under which criteria data/document could be used**

Valid Scientific Persons By Presenting Relevant Documents

**From where data/document is obtainable**

an email to corresponding author

**What processes are involved for a request to access data/document**

Accepting permission from the Shiraz University of Medical Sciences's security and confirming the receipt of the file

**Comments**