

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 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/m²

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.

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

Shiraz

Province

Fars

Postal code

7134544119

Phone

+98 71 3233 2365

Fax

+98 71 3233 2365

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

City

Shiraz

Province

Fars

Postal code

71348 -44119

Phone

+98 71 3235 2365

Fax

+98 71 3235 2365

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

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3233 2365

Email

leilaghasempour97@gmail.com

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

Gynecology and Obstetrics

Street address

Obstetrics department , Faghihi Hospital, Zand Street

City

Shiraz

Province

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Postal code

7134844119

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Email

leilaghasempour97@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Ghasempour Shirazi

Position

Infertility fellowship

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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