

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effect of GnRh Agonist short acting in IVF outcome improvement in FET cycles

#### Protocol summary

##### Study aim

Determination of the effect of short-acting GnRh agonist on Outcome IVF in the FET cycle

##### Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups

##### Settings and conduct

The study will be double-blind and the therapist and the statistician are not aware of the type of segmentation. In this study, patients who enter FET cycle were randomly divided into two groups of control and intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least two Grade A fetuses, absence of intrauterine anomaly such as adenomyosis and uterine fibroids, and uterine malformations and Clear endometrial mass, use of agonist protocol, absence of systemic diseases, vitamin D modification before initiation of ICSI. Exclusion criteria: Endometrioma identified during FET

##### Intervention groups

Control group: In this group, we are administering 2-3 tablets daily of estrogen during the second day. 10 days later the patient is referred to the clinic and endometrial thickness is measured, If the endometrial thickness is above 8, the cycle will continue the same way and then progesterone is prescribed and the transfer is done. Intervention group: Twenty-one Cinafact units a day from progesterone onset will be given to the patient from Mid luteal phase and continue the same way and then from the second day of the period we are given 2-3 tablets of estrogen, ten days later the patient returns to the clinic And the endometrial thickness is measured And then progesterone is prescribed and the transfer is done.

##### Main outcome variables

The effect of GnRh on endometrial readiness, implantation rate and clinical pregnancy outcomes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190916044781N1**

Registration date: **2019-10-13, 1398/07/21**

Registration timing: **retrospective**

Last update: **2019-10-13, 1398/07/21**

Update count: **0**

##### Registration date

2019-10-13, 1398/07/21

##### Registrant information

##### Name

Farahnaz Zandi

##### Name of organization / entity

Sarem Infertility Fertility Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4467 0883

##### Email address

dr.zandi@saremhospital.org

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of GnRh Agonist short acting in IVF outcome improvement in FET cycles

## Public title

Use of the GnRh Agonist to Improve Outcome IVF

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Have at least two embryos for transfer. The embryo has been removed from the freeze after thawing and has grade A quality. Absence of internal uterine anomalies such as adenomyosis and uterine fibroids and uterine malformations Absence of clear endometrioma Patients who used the agonist protocol in the ICSI cycle. Absence of systemic diseases (such as collagen, vascular disease, chronic hypertension, diabetes: a well-known case of diabetes with a fasting FBS of over 126) Vitamin D should be modified before starting ICSI. Age range from 25 to 40 years.

### Exclusion criteria:

Determine endometrioma during FET.

## Age

From **25 years** old to **40 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Care provider
- Data analyser

## Sample size

Target sample size: **240**

## Randomization (investigator's opinion)

Randomized

## Randomization description

This study is an interventional type study (RCT) and it was designed to compare the effect of using short-acting GnRh agonist and not using it to improve IVF results in FET cycles. Simple randomization will be done by double-blind blocking and both the therapist and the statistician are not aware of the type of divisions. Patients are provided with informed consent forms after providing sufficient explanations about the study and it will be approved and signed by them. These patients will be emphasized and will be randomly divided into different treatment groups.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The study will be double-blind and the therapist and the statistician are not aware of the type of segmentation. Patients entering FET cycle were randomly divided into control and intervention groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Hemat Highway next to MMilad, Tehran,Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Approval date

2019-02-03, 1397/11/14

#### Ethics committee reference number

IR.IUMS.REC.1397.985

## Health conditions studied

### 1

#### Description of health condition studied

Infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

### 2

#### Description of health condition studied

Endometriosis preparation for freezing embryo transfer

#### ICD-10 code

N98.9

#### ICD-10 code description

complication associated with artificial fertilization ,unspecified

## Primary outcomes

### 1

#### Description

Clinical pregnancy

#### Timepoint

Day 14 after transfer

#### Method of measurement

laboratory tests

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Twenty-one Cinafact units a day from progesterone onset will be given to the patient from Mid luteal phase and continue the same way and then from the second day of the period we are given 2-3 tablets of estrogen, ten days later the patient returns to the clinic And the endometrial thickness is measured And then progesterone is prescribed and the transfer is done.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In this group, we are administering 2-3 tablets daily of estrogen during the second day. 10 days later the patient is referred to the clinic and endometrial thickness is measured, If the endometrial thickness is above 8, the cycle will continue the same way and then progesterone is prescribed and the transfer is done.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

sarem women hospital

##### Full name of responsible person

Dr. Farahnaz Zandi

##### Street address

Sarem Women's Hospital,Phase 3- Ekbatan Town, Tehran, iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1396956111

##### Phone

+98 21 4478 0883

##### Email

dr.zandi@sarem.org

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sarem Fertility and Infertility Research Center

##### Full name of responsible person

Maryam Mahmoodinia Maymand

##### Street address

Sarem Women's Hospital,Phase 3- Ekbatan Town, Tehran, iran

##### City

tehran

##### Province

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##### Postal code

1396956111

##### Phone

+98 21 4467 0883

##### Email

dr.zandi@sarem.org

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sarem Fertility and Infertility Research Center

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Sarem Fertility and Infertility Research Center

##### Full name of responsible person

Dr. Farahnaz Zandi

##### Position

Specialist

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Sarem Women's Hospital,Phase 3- Ekbatan Town, Tehran, iran

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Sarem Fertility and Infertility Research Center

**Full name of responsible person**

Dr. Farahnaz Zandi

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Specialist

**Latest degree**

Medical doctor

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

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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

**Person responsible for updating data****Contact****Name of organization / entity**

Sarem Fertility and Infertility Research Center

**Full name of responsible person**

Dr. Farahnaz Zandi

**Position**

Specialist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**