

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Effect of saline infusion ultrasonohystrography in luteal phase of previous menstrual cycle on pregnancy rate in infertile patients undergoing freeze-thawed embryo transfer cycle

#### Protocol summary

##### Study aim

Effect of saline infusion ultrasonography on pregnancy rate in infertile women undergoing freeze embryo transfer

##### Design

Randomized clinical trials, Phase 3, single blind, two arm parallel group. 70 patients will be included in the study.

##### Settings and conduct

This study is single blind and physician and outcome assessor blinded to intervention but patient aware of intervention. One nurse aware of intervention who underwent hormonal treatment with estradiol and progesterone or who underwent saline infusion in addition to hormonal treatment on day 21 of menstrual cycle. And from day 5 of the menstrual cycle, oral contraceptive pills are started and they randomly assigned into the two groups using a random number table.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: At least one prior IVF failure, aged between 18-40years old, BMI between the18 and 30, no structural pathology in the uterus. Exclusion criteria: Uterine and pelvic adhesions, A history of hypothyroidism or hyperthyroidism, prior history of three unsuccessful In vitro fertilization

##### Intervention groups

Intervention 1: Infusion of 20 ml saline in to the uterus during ultrasonography on day 21 of previous luteal phase of menstrual cycle. Intervention 2: Estrogen initiation on day 3 of menstrual cycle (Estradiol Tablet, 2mg, three time a day, iran Hormone company) and continue till freeze embryo transfer day

##### Main outcome variables

Pregnancy rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160815029374N8**

Registration date: **2020-05-19, 1399/02/30**

Registration timing: **prospective**

Last update: **2020-05-19, 1399/02/30**

Update count: **0**

##### Registration date

2020-05-19, 1399/02/30

##### Registrant information

##### Name

Marzieh Zamaniyan

##### Name of organization / entity

Mazandaran University of Medical Sciences, Sari, Iran.

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 5724

##### Email address

m.zamaniaan@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-09-22, 1399/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effect of saline infusion ultrasonohystrography in luteal phase of previous menstrual cycle on pregnancy rate in infertile patients undergoing freeze-thawed embryo transfer cycle

### Public title

Effect of saline infusion ultrasonohystrography in luteal phase of previous menstrual cycle on pregnancy rate in infertile patients undergoing freeze-thawed embryo transfer cycle

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All patients have at least one IVF loss between the ages of 18 and 40 years BMI of patients between 18 and 30 who had no structural pathology in their uterus

#### Exclusion criteria:

Patients with uterine and pelvic adhesions  
Hypothyroidism and hyperthyroidism have been reported  
A failed IVF three-time history or 10 embryo transplants have previously been combined, and pregnancy has not occurred

### Age

From **18 years** old to **40 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Investigator

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple, individual, and randomized table methods will be divided into two groups, and only the nurse will know which patient is being treated with hormone-only estradiol plus progesterone, or saline injection on day 21 of the cycle in addition to hormone therapy. The doctor does not know which patient should be treated, but the patient knows.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Only the nurse knows which patient is being treated with hormone-only estradiol plus progesterone, or saline injection on day 21 of the cycle in addition to hormone therapy. The doctor does not know which patient should be treated, but the patient does not know which treatment to treat, but the patient knows.should be treated, but the patient knows.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in the research of Imam Sari Educational and Medical Hospital - Mazandaran  
Universi

##### Street address

Amir Mazandarani Boulevard, Imam Khomeini  
Hospital

##### City

sari

##### Province

Mazandaran

##### Postal code

33131 - 48166

#### Approval date

2020-01-28, 1398/11/08

#### Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.170

## Health conditions studied

### 1

#### Description of health condition studied

Infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Clinical pregnancy

#### Timepoint

4 to 5 weeks after embryo transfer

#### Method of measurement

Test - Ultrasound

## Secondary outcomes

### 1

#### Description

Miscarriage rates

#### Timepoint

Till twenty weeks after embryo transfer

#### Method of measurement

Questionnaire

## 2

### Description

Chemical pregnancy rate

### Timepoint

Two weeks after embryo transfer

### Method of measurement

B-HCG Kit

## Intervention groups

### 1

#### Description

Intervention group: Saline ultrasonography with 20 ml saline infusion on day 21 of late lutea phase of prior cycle

#### Category

Treatment - Other

### 2

#### Description

Control group: Estrogen initiation on day 3 of menstrual cycle (2 mg tab, Iran Hormone company) three time a day and continuous to embryo transfer day.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital in Sari

##### Full name of responsible person

Marzieh Zamanian

##### Street address

No. 233, ground floor section, ground floor, Imam Khomeini Hospital, Amir Mazandarani St.

##### City

sari

##### Province

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##### Postal code

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##### Phone

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m.zamanian@mazums.ac.ir

##### Web page address

<https://www.mazums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Fereshteh Akrami

#### Street address

N0.2, Third floor, Department of Research and Technology, Teachers' Square

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#### Phone

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f.akrami1919@gmail.com

#### Web page address

<https://www.mazums.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Marzieh Zamanian

##### Position

MD, Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Reproductive Health

##### Street address

Ground floor, IVF ward, NO 233, Imam Khomeini Hospital, Amirmazandarani Ave

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Marzieh Zamanin

**Position**

Asistant professor M.D.

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Marzieh Zamani

**Position**

Assistant professor MD

**Latest degree**

Specialist

**Other areas of specialty/work**

Reproductive Health

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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