

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)

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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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fereshteh Akrami

Street address

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

Assistant professor MD

Latest degree

Specialist

Other areas of specialty/work

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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