Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of pregnancy results in IVF cycles with luteal phase support with progesterone, prolotex, and Cyclogest in infertility center.

Protocol summary

Study aim

Comparison of pregnancy outcomes with the use of three types of progesterone in IVF cycles including subcutaneous Prolotex; Progesterone injections and Cyclogest suppositories to support the uterus.

Design

Three-group randomized clinical trial; Phase 4 is performed on 309 infertile women. Randomization is performed on one of three treatment groups with an equal number of patients using a table of random numbers from 1-309.

Settings and conduct

This study is performed as a clinical trial in the infertility center of Imam Khomeini Hospital in Tehran in 1998-99. Infertile IVF candidates are divided into three treatment groups with equal numbers of patients using a random number table and receive muscle progesterone, vaginal suppository, Cyclogest, and subcutaneous Prolotex, respectively.

Participants/Inclusion and exclusion criteria

Infertile women aged 18-42 years; BMI less than 30 and a history of less than three IVF cycles are included in the study. Cases of fibroids; Severe endometriosis; Hydrosalpinx and underlying diseases are among the cases not included in the study.

Intervention groups

To transfer the frozen fetus on the second day of menstruation, 2 mg estradiol valerate tablets are given three times a day for 9 days, and if there is an endometrium with a thickness of more than 7 mm in the first group, 100 mg of progesterone ampoule daily; In the second group, vaginal Cyclogest suppository 400 mg twice a day and in the third group, Subcutaneous Prolotex ampoules 25 mg daily; is prescribed up to 12 weeks of pregnancy.

Main outcome variables

Clinical pregnancy is the main outcome of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141217020351N12**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-06, 1399/09/16**
Update count: **0**

Registration date

2020-12-06, 1399/09/16

Registrant information

Name

Ensieh Shahrogh Tehraninejad

Name of organization / entity

Tehran University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of pregnancy results in IVF cycles with luteal phase support with progesterone, prolotex, and Cyclogest in infertility center.

Public title
Evaluation of pregnancy outcomes in IVF cycles with uterine support with progesterone, Prolotex, and Cyclogest in the infertility center.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women aged 18 to 42 years BMI less than 30 Having less than three IVF cycles FSH < 15 U/L Estradiol less than 80 pg / ml Having a normal uterine cavity on a recent hysteroscopy, sonohistogram, or hysterosalpingogram
Exclusion criteria:
Intramural fibroids deforming the uterine cavity Endometriosis stage three and four Hydrosalpinx History of poor response to treatment Spontaneous abortion Adrenal disease Thyroid disease Thromboembolic diseases

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

Gender
Female

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **309**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed to one of three treatment groups with an equal number of patients using a random number table; In the order that we look from the top to the bottom of the table and patients enter the study randomly and in the order of the random number table; So that the researcher touches one of the numbers and then moves in the specified direction and records the numbers and assigns them to different groups. Patients in the first group, 1-100, the second group, 101-200, and the third group, 201-309, receive progesterone, Cyclogest, and Prolotex, respectively.

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
Vice -Chancellar in Research Affairs -Tehran University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard.
City
Tehran
Province
Tehran
Postal code
۵۳۷۶۱-۱۴۱۷۶

Approval date
2019-03-10, 1397/12/19

Ethics committee reference number
IR.TUMS.VCR.REC.1398.1024

Health conditions studied

1

Description of health condition studied
Types of female infertility

ICD-10 code
N97.9

ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
Clinical Pregnancy

Timepoint
Ten weeks after starting treatment

Method of measurement
Blood tests and ultrasound

Secondary outcomes

1

Description
Abortion

Timepoint
10 weeks after embryo transfer

Method of measurement
Blood tests and ultrasound

2

Description
Ectopic Pregnancy

Timepoint

5 weeks after embryo transfer

Method of measurement

Blood tests and ultrasound

Intervention groups

1

Description

Intervention group:In the first group; To transfer the frozen fetus on the second day of menstruation, 2 mg of Estradiol Valerate tablets are given three times a day for 9 days, and if there is an endometrium with a thickness of more than 7 mm, 100 mg of progesterone ampoule daily until 12 weeks of pregnancy is prescribed.

Category

Treatment - Drugs

2

Description

Intervention group:In the second group; To transfer the frozen fetus on the second day of menstruation, 2 mg Estradiol Valerate tablets are given three times a day for 9 days, and if there is an endometrium with a thickness of more than 7 mm, a Cyclogest suppository 400 mg twice a day for up to 12 weeks of Pregnancy is prescribed.

Category

Treatment - Drugs

3

Description

Intervention group:In the third group; To transfer the frozen fetus on the second day of menstruation, 2 mg Estradiol Valerate tablets are given three times a day for 9 days. If there is an endometrium with a thickness of more than 7 mm, Prolotex 25 mg daily, subcutaneously for up to 12 weeks of Pregnancy is prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeni Hospital Complex, Vali-Asr Infertility Clinic.

Full name of responsible person

Ensieh Shahrokh Tehraninejad

Street address

Keshavarz Blvd, Imam Khomeini Hospital Complex,Vali-Asr Infertility Clinic.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maedeh Ahmadi Dastjerdi

Position

Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Fedyeh Haghollahi
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Researcher
Latest degree
Master
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