Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Subcutaneous progesterone (Prolutex) versus vaginal (Cyclogest) for luteal phase support in IVF/ICSI cycles: a randomized controlled clinical trial study phase 3

Protocol summary

Summary

This study is planned to evaluate the efficacy and tolerability of subcutaneous administration of progesterone compared with vaginal progesterone for luteal phase support in cycles IVF / ICSI in referring patients to the Royan Institute. A randomized controlled clinical trial is conducted during 1393 to 1394 in the Royan Institute. After ovum pick up, eligible women were randomly allocated into two groups (group A and B). luteal phase support is done in two ways: subcutaneous injection of progesterone (Prolutex) and vaginal suppository. In the Group A (n = 70), since ovum pick up day, a daily subcutaneous injections of progesterone (25 mg) (Prolutex®; IBSA Institut, SA Biochimique) will be used and in the Group B (n= 70), one vaginal suppository will be used (Cyclogest ®; Actavis, Barnstaple, UK), If pregnancy is occurred it continues until 10 weeks of pregnancy. Sixteen days after embryo transfer, as well as 6 and 10 weeks of pregnancy, possible side effects (gastrointestinal, skin, and local), pain and discomfort during use of the drugs will follow by the designed questionnaire and will be recorded. Side-effect, clinical pregnancy and abortion rates will be compared between two groups by appropriate statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402191141N18**
Registration date: **2015-02-19, 1393/11/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-02-19, 1393/11/30

Registrant information

Name
Kiandokht Kiani
Name of organization / entity
Royan Institute
Country
Iran (Islamic Republic of)
Phone
+98 21 2230 7960
Email address
kiandokht.kiani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Royan Institute and Shafayab gostar pharmaceutical company

Expected recruitment start date

2015-02-21, 1393/12/02

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Subcutaneous progesterone (Prolutex) versus vaginal (Cyclogest) for luteal phase support in IVF/ICSI cycles: a randomized controlled clinical trial study phase 3

Public title

Subcutaneous progesterone versus vaginal suppository for luteal phase support in assisted reproductive technology cycles in patients referred to Royan Institute

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Female age 19–39 years ; An written consent to participate in the study ;Body mass index (BMI) <30 kg/m2 Exclusion Criteria: Severe male infertility (TESE, PESA) ; The uterine cause of infertility (uterine surgery history, cervical insufficiency, submucosal myoma or intramural fibroids ≥ 5 cm and multiple uterine polyps) ; Patients with poor ovarian response or patients with reduced ovarian reserve (FSH ≥ 15 IU/ml, AMH ≤ 1 ng/ml) ; Tubal factor was diagnosed as hydrosalpinx ; Moderate and severe endometriosis (stage3and 4) ; Cases of repeated implantation failure (RIF) and spontaneous abortions.

Age
From **19 years** old to **39 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Royan Institute

Street address
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City
Tehran

Postal code

Approval date
2015-01-13, 1393/10/23

Ethics committee reference number
1102/93/EC

Health conditions studied

1

Description of health condition studied
Other complications associated with artificial fertilization

ICD-10 code
N98

ICD-10 code description
Complications associated with artificial fertilization

Primary outcomes

1

Description
Clinical pregnancy rate

Timepoint
Evidence of pregnancy by clinical (fetal heartbeat) or ultrasound parameters (ultrasound visualization of a gestational sac, embryonic pole with heartbeat)after 7-6 weeks after embryos transfer

Method of measurement
Vaginal sonography

2

Description
Pain during drug use

Timepoint
The patient records pain during drug using based on visual scale from 0 to 10

Method of measurement
Visual analog scale

3

Description
Comfort and satisfaction of drug

Timepoint
The patient records comfort and satisfaction during drug using based on visual scale from 0 to 10

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Early Miscarriage rate

Timepoint
spontaneous loss of a pregnancy before 12 weeks

Method of measurement
Vaginal sonography

Intervention groups

1

Description
Intervention: Luteal phase support during ART treatment with subcutaneous injections of progesterone (Prolutex): since ovum pick up day, a daily subcutaneous injection

of progesterone (25 mg) (Prolutex®; IBSA Institut, SA Biochimique) will be used and if pregnancy is occurred it continues until 10 weeks of pregnancy.

Category

Treatment - Drugs

2

Description

Control group : Luteal phase support during ART treatment using a vaginal suppository (Cyclogest) : Since ovum pick up day, one vaginal suppository every 12 hours will be used (Cyclogest ®; Actavis, Barnstaple, UK), If pregnancy is occurred it continues until 10 weeks of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Dr Moini

Street address

Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Dr.Abdolhossein Shahverdi

Street address

: Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Royan Institute

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Shafayab Gostar company

Full name of responsible person

Elham Sahafi

Street address

275 number , after Modarres Bridge , beheshti Street.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shafayab Gostar company

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Dr Ashraf Moini

Position

Gynecologist / Professor

Other areas of specialty/work

Street address

: Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 2356 2640

Fax

Email

a_moini@royaninstitute.org

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Dr Ashraf Moini

Position

Giynicologist / Professor

Other areas of specialty/work

Street address

: Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 2356 2640

Fax

Email

a_moini@royaninstitute.org

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Arezoo Arabipoor

Position

M.Sc of midywiferry

Other areas of specialty/work

Street address

: Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 2356 2640

Fax

Email

arezoo.arabipoor@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty