

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of endometrial local injury in increasing pregnancy rate in patients undergoing ART (IVF/ICSI)

Protocol summary

Summary

Implantation of the human embryo is the limiting factor in the success of invitro-fertilization and embryo transfer (IVF-ET). We wanted to find out whether creating a local injury to the endometrium in the non-transfer cycle would improve the IVF-ET outcome in the subsequent cycle. We believe that the injury created causes release of substances which help in implantation. Study Design and Subjects: This is a randomized control study designed to evaluate the effect of local injury to the endometrium in non-transfer cycle in patients with previous failed IVF (at least ≥ 1 cycles have failed). Patients will be randomly allotted to control and intervention group. The patients in the intervention group Pipelle endometrial sampling 19-21th day (biopsy in luteal) in the cycle prior to IVF transfer cycle. Outcome Measures: Clinical pregnancy rate, implantation rate and ongoing pregnancy rate

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Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2013-04-03, 1392/01/14

Expected recruitment end date

2014-02-04, 1392/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302091141N13**

Registration date: **2013-03-07, 1391/12/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-07, 1391/12/17

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Scientific title

Evaluating the effect of endometrial local injury in increasing pregnancy rate in patients undergoing ART (IVF/ICSI)

Public title

The effect of endometrial local injury in increasing pregnancy rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Previous failed In-vitro fertilization embryo transfer cycle (at least ≥ 1 cycles have failed); Patients who are good responders and have good quality embryos in the previous attempts; Age of patients up to 40 years. Exclusion Criteria: Those with intramural fibroid distorting the endometrial cavity/sub-mucous myoma; Those with sonographically detected hydrosalpinx; age over than 40 years old; poor responders to ovarian stimulation.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **220**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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**

2013-02-04, 1391/11/16

Ethics committee reference number

EC/91/1132

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

4-6 weeks after embryo transfer

Method of measurement

Ultrasound visualization of a gestational sac

Secondary outcomes**1****Description**

Biochemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

BhCG test

2**Description**

Implantation

Timepoint

4-6 weeks after embryo transfer

Method of measurement

Number of sacs by Sonography

3**Description**

Endometrial thickness

Timepoint

Third day

Method of measurement

Sonography

4**Description**

Early abortion

Timepoint

Week 12

Method of measurement

Sonography

5**Description**

Late abortion

Timepoint

Week 20

Method of measurement

Sonography

Intervention groups**1****Description**

Pipelle endometrial sampling 19-21th day in the cycle prior to IVF transfer cycle.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Dr Mahnaz Ashrafi

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Dr Mahnaz Ashrafi

Street address

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

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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

100

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 Mahnaz Ashrafi

Position

Gynecologist/Head of Endocrinology and Female Infertility Department of Royan Institute

Other areas of specialty/work**Street address**

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Person responsible for updating data

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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