

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### A randomized clinical trial to evaluate the effect of endometrial scratch injury on clinical pregnancy rate in patients with intrauterine insemination failures ( compared with no intervention control group)

#### Protocol summary

2016-02-03, 1394/11/14

#### Summary

Present study is designed as a randomized clinical trial non-blinded phase 3. On hundred fifty infertile patients with IUI failure attending to Imam-Khomeini Hospital and Royan Institute during a 12-month period 2013 and 2014 were enrolled. The eligible patients are randomly assigned in two groups by using block randomization method. In the experimental group, all patients will undergo endometrial biopsy at days 8-9 of stimulation phase in present IUI cycle (n=75). Endometrial scratch by a sterile by Pipelle (made in USA) was performed. Endometrial scratch by a sterile by Pipelle (made in America distributor trade wise) is performed. Patients in the control group (n=75) have received no intervention. When at least one follicle size 18-20 mm, one HCG ampule will be injected and after 36 hours, IUI will be performed. After IUI, luteal phase will be supported by 400 mg daily intra-vaginal progesterone suppository. Chemical pregnancy will be evaluated by Beta hCG test 12 to 14 days after IUI. Clinical pregnancy is approved by observation of gestational sac in ultrasound evaluation. Primary and secondary outcomes are including the chemical, clinical pregnancy and early miscarriage rates and endometrial thickness on HCG day will be compared between the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201507271141N19**

Registration date: **2016-02-03, 1394/11/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### 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

Vice chancellor for research of Royan Institute

#### Expected recruitment start date

2013-12-31, 1392/10/10

#### Expected recruitment end date

2014-12-31, 1393/10/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A randomized clinical trial to evaluate the effect of endometrial scratch injury on clinical pregnancy rate in patients with intrauterine insemination failures ( compared with no intervention control group)

#### Public title

The effect of endometrial scratch on the fertility rate in patients with failure of intrauterine insemination treatment cycles

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion Criteria: Patients with two or more IUI cycles failures; patients with normal uterine anatomy or normal hysterosalpingography. Exclusion Criteria: The women over forty years old; uterine myoma or polyps; patients with tubal infertility; patients with severe male factor infertility; patients with moderate or severe endometriosis; Patients with a body mass index more than 30 kg/m<sup>2</sup>

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**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**

Ethics committee of 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**

2015-12-08, 1394/09/17

**Ethics committee reference number**

IR.ACECR.ROYAN.REC.1394.54

**Health conditions studied****1****Description of health condition studied**

Female infertility

**ICD-10 code**

N97.9

**ICD-10 code description**

Female infertility,unspecified

**Primary outcomes****1****Description**

Chemical pregnancy rate

**Timepoint**

12 to 14 days after IUI

**Method of measurement**

Number and percent of positive Beta hCG test cases

**2****Description**

Clinical pregnancy rate

**Timepoint**

5 to 6 weeks after IUI

**Method of measurement**

Number and percent of cases with observed gestational sac on transvaginal ultrasound

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

Endometrial thickness on HCG day

**Timepoint**

On the day of HCG injection

**Method of measurement**

Endometrial thickness (mm) in transvaginal ultrasound evaluation

**2****Description**

Early miscarriage rate

**Timepoint**

The loss of a pregnancy before 12 weeks of pregnancy after intervention

**Method of measurement**

Number and percent of cases with bleeding and excretion gestation products (Observed no fetal heartbeat on ultrasound)

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

In the intervention group: on 9 -8 cycle day, endometrial scratch (biopsy) by a experienced physician is performed by using a sterile Pipelle.

**Category**

Treatment - Other

## 2

### Description

Patients in the control group have received no intervention

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran University of Medical Sciences and Royan Institute

##### Full name of responsible person

Mansoureh Haghiri (M.D)

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of 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

##### City

Tehran

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research of 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 Mansoureh Haghiri

#### Position

MD(Gynecologist)

#### 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

aciyehaghiri@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Royan Institute

##### Full name of responsible person

Dr Mahnaz Ashrafi

##### Position

Gynecologist / Associate Professor of Iran University of Medical Sciences

##### Other areas of specialty/work

##### Street address

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ashrafim@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

Master of Sciences in Midwifery / researcher

##### Other areas of specialty/work

##### Street address

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Arezoo.arabipoor@gmail.com

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*