

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)

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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/m²

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

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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

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

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Person responsible for updating data

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Full name of responsible person

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Master of Sciences in Midwifery / researcher

Other areas of specialty/work

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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