

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of local endometrial injury in women with one and two failure history in IVF cycle on success rate of embryo implantation and pregnancy

Protocol summary

Summary

This study is a randomized, single-blind clinical trial conducted in parallel and single-center. The aim of this study is to evaluate the effect of mechanical injury on pregnancy rate. Patients aged between 15 to 40 years old are enrolled in the study based on inclusion criteria. Inclusion criteria are 1 or 2 previous failure in IVF and normal uterine cavity and, all women with known intrauterine factors and active vaginal and cervical infection are excluded from study. Our sample size is 70 who are randomly allocated into two groups. In intervention group, patients are treated with Local endometrial injury (LEI) with standard Pipelle biopsy before IVF procedure in luteal phase of menstrual cycle. Then patients are treated with increasing dose of 2, 3 and 4 mg progesterone valerate suppository for 14 days. After transvaginal sonography, if endometrial thickness is more than 7 mm, progesterone cyclogest is administered and 5 days later embryo transfer is done. In control group IVF procedure is performed without LEI. The researcher is blinded to the treatment of two groups before IVF. After IVF, the rate of clinical and chemical pregnancy is analyzed between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604261556N89**
Registration date: **2016-12-28, 1395/10/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-28, 1395/10/08

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Science

Expected recruitment start date

2016-12-24, 1395/10/04

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local endometrial injury in women with one and two failure history in IVF cycle on success rate of embryo implantation and pregnancy

Public title

Effect of local endometrial injury in women with unsuccessful IVF improve on pregnancy rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age<40 years old; normal uterine cavity in hysteroscopy and Hysterosalpingography in last year; BMI<30; one or two IVF failure; not taking OCP or GnRH for FET in past cycle; patient had indication for EI
Exclusion criteria: known intrauterine factors in sonography or imaging as fibroma ; endometrial hyperplasia ; cancer; active vaginal and cervical infection; presence of hydrosalpinx or systemic disorders

Age

From **15 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization is based on randomized blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Qods Street, Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2015-10-29, 1394/08/07

Ethics committee reference number

IR.TUMS.REC.1394.1289

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

Z31.2

ICD-10 code description

Admission for harvesting or implantation of ova

Primary outcomes

1

Description

pregnancy

Timepoint

2 weeks after IVF

Method of measurement

beta HCG test

2

Description

implantation

Timepoint

5 weeks after IVF

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, patients are treated with Local endometrial injury (LEI) with standard Pipelle biopsy before IVF procedure in luteal phase of menstrual cycle. Then patients are treated with increasing dose of 2, 3 and 4 mg progesterone valerate suppository for 14 days. After trans vaginal sonography, if endometrial thickness is more than 7 mm, progesterone cyclogest is administered and 5 days later embryo transfer is done.

Category

Treatment - Other

2

Description

Control group: IVF procedure is performed without LEI.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Soodeh Khorasani

Street address

Arash Hospital, Rashid Street, Tehranpars, Resalat

Highway
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Tehran University of Medical Science

Full name of responsible person

Masoud Younesian

Street address

Tehran University of Medical Science, Qods street, Keshavarz boulevard

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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, Tehran University of Medical Science

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

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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

