

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of successful pregnancy rate after IVF between patients with hysteroscopy and endometrial biopsy and patients with hysteroscopy without biopsy during treatment cycle

Protocol summary

Summary

The purpose of this study is comparison of successful pregnancy rate after IVF between patients with hysteroscopy and endometrial biopsy and patients with hysteroscopy without biopsy during treatment cycle. Women who are referred to the Shariati infertility center for IVF for the first time will be entered. Patients with uterine anomalies; endometriosis; uterine myoma; IVF failure and those with an azoospermic partners will be excluded. After signing an informed consent 44 patients with the same protocol at the same day of the cycle (8th day) will be allocated to one of the therapeutic groups including only hysteroscopy (22 patients) or hysteroscopy plus endometrial biopsy (22 patients). Under general anesthesia and using Claw forceps during hysteroscopy, a 2mm endometrial biopsy will be taken from the posterior surface of endometrium -1.5 cm inferior to the fundus. Procedure takes about 5 minutes. Clinical pregnancy as a primary outcome will be comparison between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015013020871N1**

Registration date: **2015-04-13, 1394/01/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-13, 1394/01/24

Registrant information

Name

Aida Najafian

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0050

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anajafian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of successful pregnancy rate after IVF between patients with hysteroscopy and endometrial biopsy and patients with hysteroscopy without biopsy during treatment cycle

Public title

Effect of hysteroscopy on increase of pregnancy rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women who are referred for IVF for the first time; age:18-35 years Exclusion criteria: previous history of IVF failure; uterine anomaly; endometriosis ; uterine myoma; those whose partner has azospermia.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science

Street address

Keshavarz Bulvar-Ghods Street

City

Tehran

Postal code**Approval date**

2015-01-21, 1393/11/01

Ethics committee reference number

9211400003-135977

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

5 weeks after intervention

Method of measurement

Gestational Sac and Fetal Heart Rate

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

Chemical Pregnancy

Timepoint

3 weeks after intervention

Method of measurement

Serum BhCG level

2**Description**

Implantation Rate

Timepoint

5 weeks after intervention

Method of measurement

Number of gestational sac divided by the number of embryos transfer

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

In the control group after general anesthesia with mask under hysteroscopic guid we irrigate uterine cavity.

Category

Treatment - Surgery

2**Description**

In the intervention group after general anesthesia with mask under hysteroscopic guid with claw forceps we take a 2 mm biopsy 1.5 cm below the fundus. Time of surgery is about 5 minutes.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Center of Shariati Hospital

Full name of responsible person

Dr.Aida Najafian-Infertility Fellowship

Street address

North Kargar-Serahe Jamaledin Asad Abadi

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Reasearch Center of Tehran University of Medical
Science- Shariati Hospital

Full name of responsible person

Dr Yoonesi

Street address

Ghods street

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Reasearch Center of Tehran University of Medical
Science- Shariati Hospital

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**

Tehran University of Medical Science- Shariati
Hospital

Full name of responsible person

Aida Najafian

Position

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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