

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of diagnostic hysteroscopy findings in patients candidate for ART (IVF, ICSI) and its effect on pregnancy rate Compared to control group.

Protocol summary

Summary

Candidates for ART (ICSI ,IVF) for the first time are enrolled,with the inclusion criteria of normal hysterosonography, normal vaginal ultrasound during the past 12 months ; age between 25-40 years; absence of abnormal uterine bleeding; no past history of hysteroscopy performed in the last 6 months. Patients are going to be randomly assigned to two groups based on computerized lists. In the case group, hysteroscopy would be performed and abnormal findings like cervical and uterine anatomical disorders ,fibrosis , myoma or polyp and etc would be registered and lesions like submucosal myomas or polyps and uterine adhesions would be removed.Also an endometrial biopsy would be undertaken and the sample would be sent for histological examination . In control group hysteroscopy is not done. The ART cycle in both groups is started from the 21th day of the following menstrual cycle by prescribing 0.2 cc Suprefact(short acting GnRH analogue) subcutaneously for at least 10 days and after beginning of the next menstrual cycle , depending on the patients third day FSH level ,induction of ovulation is started with 2-5 ampoules of 75 IU HMG or Gonal-f . After serial sonographic monitoring of follicular development , when at least two follicles> 18 mm are reported, the patient receives 10000 IU HCG and ovum pick up(OPU)is done 36 hours there after . 2 or 3 embryos are transferred on day 3 after OPU and β -HCG is tested on the 14th day of embryo transfer to investigate biochemical pregnancy. .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208152565N6**

Registration date: **2012-10-08, 1391/07/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-08, 1391/07/17

Registrant information

Name

Farnaz Sohrabvand

Name of organization / entity

Vali-E _Asr Reproductive Health Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6693 9320

Email address

sohrabva@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Tehran University of Medical Sciences

Expected recruitment start date

2012-06-10, 1391/03/21

Expected recruitment end date

2014-06-10, 1393/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of diagnostic hysteroscopy findings in patients candidate for ART (IVF, ICSI) and its effect on pregnancy rate Compared to control group.

Public title

Evaluation of diagnostic hysteroscopy findings in patients candidate ART (IVF, ICSI)

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion Criteria:Hysterosalpingography normal during the past 12 month;Normal vaginal ultrasound TVS;Age between 25-40 year;The absence of abnormal uterine bleeding (AUB) and lack of hysteroscopy performed in the last 6 months. Exclusion Criteria:Abnormal uterine bleeding; hysteroscopy performed in the last 6 months;Abnormal Vaginal Ultrasound .

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd Tehran University Building

City

Tehran

Postal code

Approval date

2012-08-22, 1391/06/01

Ethics committee reference number

17153

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N.97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes

1

Description

Pathologic findings on hysteroscopy

Timepoint

During the hysterectomy

Method of measurement

View the eyes and Biopsy

2

Description

Polip

Timepoint

During the hysteroscopy

Method of measurement

View the eyes and Biopsy

3

Description

Adhesion

Timepoint

During the hysteroscopy

Method of measurement

View the eyes and Biopsy

4

Description

Fibroma

Timepoint

During the hysteroscopy

Method of measurement

View the eyes and Biopsy

Secondary outcomes

1

Description

Impact on IVF outcomes

Timepoint

14 days after embryo transfer

Method of measurement

Blood Tests

Intervention groups

1

Description

Control Group:Hysterodcopy is not done

Category

Treatment - Devices

2

Description

In the case group Hysteroscopy is performed , submucosal myoma or polyps 1 cm or larger cervical or uterine adhesions within Chonnell ,with hysteroscopy will be resolved , If this is not possible with Resectoscopy pathology resolved and The example is sent for histological examination.In the Normal hysteroscopy, biopsy is sent for histological examination .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility center in Valie-Asr Hospital

Full name of responsible person

Dr,Farnaz Sohrabvand

Street address

Vali-E-Asr Reproductive Health Research center ,Valieasr Hospital ,Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Tehran University of Medical Sciences

Full name of responsible person

Dr.Younesian

Street address

Keshavarz Boulevard - The Quads - Tehran Medical University building - floors5

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Tehran University of Medical Sciences

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

Vali-e-Asr reproductive HealthnResearch center

Full name of responsible person

Farnaz Sohrabvand

Position

scientific faculty

Other areas of specialty/work

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Person responsible for updating data

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Haghollahi Fedyeh

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M.SC

Other areas of specialty/work

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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