

# 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  $\beta$ -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

##### City

Tehran

## 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

#### Street address

Valie -Asr Hospital

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fsohrabvand@yahoo.com

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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Scientific faculty

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## Person responsible for updating data

### Contact

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Haghollahi Fedyeh

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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*