

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### To evaluate the effect of low dose Aspirin in increasing the chance of pregnancy in frozen embryo transfer cycles

#### Protocol summary

##### Summary

It has been reported that low-dose aspirin and Heparin would lead to an increased pregnancy rate in patients undergoing IVF-ET. Low-dose aspirin may improve uterine and ovarian perfusion and that aspirin might enhance endometrial receptivity and ovarian responsiveness as well, which could result in better implantation and pregnancy rates after IVF or ICSI treatment. This study assesses potential effects of low-dose aspirin (100 mg daily) on pregnancy rate following frozen embryo transfer. In the present randomized double-blind prospective study, the patients will be randomly assigned to the study and control groups. With the onset of endometrial preparation and estrogen treatment, the study group will receive 100 mg of oral aspirin and the control group will be given placebo. When endometrial thickness will be found between 8-14 mm, therapy with progesterone (100 mg IM daily) will be started and embryo transfer will be performed 48 to 72 hours later. Doppler ultrasonography also is done to calculate resistive index (RI) and pulsatility index (PI), the day after progesterone administration.  $\beta$ HCG will be assessed 14 days after ET. If a pregnancy will be achieved, the patients in study and control groups will be instructed to continue the aspirin or placebo through 5 weeks and if the pregnancy test result will be negative, the treatment with aspirin or placebo will be stopped. Vaginal sonography will be done 2 weeks after the positive result of pregnancy for observation of gestational sac. At first, the study will be performed on 60 patients (30 in each group) as a pilot study. Then the sample size will be calculated by the results.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201205131141N12**

Registration date: **2012-07-13, 1391/04/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-07-13, 1391/04/23

##### Registrant information

###### Name

Kiandokht Kiani

###### Name of organization / entity

Royan Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2230 7960

###### Email address

kiandokht.kiani@royaninstitute.org

##### Recruitment status

**Recruitment complete**

##### Funding source

Royan Institute

##### Expected recruitment start date

2012-05-01, 1391/02/12

##### Expected recruitment end date

2015-02-07, 1393/11/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

To evaluate the effect of low dose Aspirin in increasing the chance of pregnancy in frozen embryo transfer cycles

##### Public title

The effect of low dose Aspirin in increasing the chance of pregnancy

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Patients with "long or antagonist" protocol; Women who did not achieve a pregnancy following a fresh embryo transfer or women whom their embryos had not been transferred due to OHSS; The women who had frozen embryos available for another transfer. Exclusion Criteria: The patients with history of recurrent abortion, contraindications for aspirin.

### **Age**

From **18 years** old to **40 years** old

### **Gender**

Female

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

The patients will be followed until 20 weeks of gestation and the results of treatment cycle will be compared in two groups. Data analysis will be performed by means of SPSS software program.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Royan Institute

##### **Street address**

Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way

##### **City**

Tehran

##### **Postal code**

16635148

#### **Approval date**

2011-02-15, 1389/11/26

#### **Ethics committee reference number**

1065/ 89/ EC

## **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**

4-6 weeks after embryo transfer

#### **Method of measurement**

Ultrasound visualization of a gestational sac

## **Secondary outcomes**

### 1

#### **Description**

Implantation rate

#### **Timepoint**

4-6 weeks after embryo transfer

#### **Method of measurement**

Number of sacs by Sonography

### 2

#### **Description**

Early abortion

#### **Timepoint**

Week 12

#### **Method of measurement**

Sonography

### 3

#### **Description**

Biochemical pregnancy

#### **Timepoint**

2 weeks after embryo transfer

#### **Method of measurement**

BhCG test

### 4

#### **Description**

Endometrial thickness

#### **Timepoint**

Third day & Embryo transfer day

#### **Method of measurement**

Sonography

## 5

### Description

Late abortion

### Timepoint

Week 20

### Method of measurement

Sonography

## Intervention groups

### 1

#### Description

With the onset of endometrial preparation and estrogen treatment, the study group will receive 100 mg of oral aspirin.

#### Category

Treatment - Drugs

### 2

#### Description

With the onset of endometrial preparation and estrogen treatment, the control group will receive placebo.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Royan Institute

##### Full name of responsible person

Dr.Tahereh Madani

##### Street address

Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Royan Institute

##### Full name of responsible person

Dr. Ahmad Vosugh

##### Street address

Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

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

Roan Institute

#### Full name of responsible person

Dr.Tahereh Madani

#### Position

gynecologist

#### Other areas of specialty/work

#### Street address

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#### Email

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#### Web page address

www.royaninstitute.org

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Dr Tahereh Madani

#### Position

Gynecologist

#### Other areas of specialty/work

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr.Tahereh Madani

**Position**

Gynecologist

**Other areas of specialty/work****Street address**

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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*

**Data Dictionary**

*empty*