

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. β 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

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

City

Tehran

Postal code

Iran

Phone

+98 21 2235 2008

Fax

+98 21 2230 6481

Email

tmadani@royaninstitute.org

Web page address

www.royaninstitute.org

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Dr Tahereh Madani

Position

Gynecologist

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

1663

Phone

+98 21 2235 2000

Fax

+98 21 2230 6481

Email

tmadani@royaninstitute.org5148

Web page address

www.royaninstitute.org

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

Royan Institute

Full name of responsible person

Dr.Tahereh Madani

Position

Gynecologist

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

Address: Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Postal code

16635148

Phone

+98 21 2235 2000

Fax

+98 21 2230 6481

Email

tmadani@royaninstitute.org

Web page address

www.royaninstitute.org

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