

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison between FSH administration with HCG and HCG alone at the time of trigger in IVF cycles outcomes

#### Protocol summary

##### Study aim

The aim of this randomized clinical trial is comparison of the effect of FSH (follicle - stimulating hormone) administration plus HCG(human chorionic gonadotropin) at the time of oocyte trigger and HCG alone on IVF cycles outcomes as well as ovarian hyperstimulation syndrome.

##### Design

A total of 109 women who met inclusion criteria, who were convinced about the research design and signed a written consent form were divided into two groups during a not-blinded, phase 2, parallel groups, without control group randomized clinical trial.

##### Settings and conduct

Regarding the importance of oocyte triggering in IVF cycles, 109 women at Yazd Research and Clinical Center who were candidate for IVF, were randomly divided into two groups for oocyte triggering (one group using FSH plus hCG or hCG alone in another group).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women undergoing IVF and GnRH antagonist protocol. Non inclusion criteria: severe male factor infertility, cycle cancellation due to changing to intrauterine insemination and freeze-all policy, a cycle containing preimplantation genetic diagnosis (PGD) and estradiol level of more than 2500 pg/mL, donor or surrogate cycle.

##### Intervention groups

Intervention group 1: Oocyte triggering using FSH plus hCG; Intervention group 2: Oocyte triggering using hCG alone

##### Main outcome variables

Clinical pregnancy; oocyte recovery rate; oocyte maturity rate; fertilization proportion rate; fertilization rate; implantation rate; chemical pregnancy

#### General information

##### Reason for update

Updating the clinical trial according to the last changes in

case number and results

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017082724512N5**

Registration date: **2017-09-22, 1396/06/31**

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

Last update: **2021-03-23, 1400/01/03**

Update count: **2**

##### Registration date

2017-09-22, 1396/06/31

##### Registrant information

###### Name

Abbas Aflatoonian

###### Name of organization / entity

Yazd research and clinical center for infertility

###### Country

Iran (Islamic Republic of)

###### Phone

+98 358247085

###### Email address

abbas-aflatoonian@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Yazd Reproductive Sciences Institute ,Shahid Sadoughi University of Medical Sciences.

##### Expected recruitment start date

2017-08-01, 1396/05/10

##### Expected recruitment end date

2018-01-20, 1396/10/30

##### Actual recruitment start date

2017-08-01, 1396/05/10

##### Actual recruitment end date

2017-10-07, 1396/07/15

##### Trial completion date

2017-11-30, 1396/09/09

## Scientific title

Comparison between FSH administration with HCG and HCG alone at the time of trigger in IVF cycles outcomes

## Public title

The effect of FSH administration with HCG at the time of trigger on IVF cycles outcomes

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Infertile women who candidate for IVF cycles underwent GnRH antagonist protocol Fresh embryo transfer cycles

### Exclusion criteria:

Women with history of endocrine disorders serum estradiol>2500pg/ml in day of trigger Intrauterine abnormality (uterine polyp; uterine myoma) Severe male factor Cycle cancellation or changing to intrauterine insemination A cycle containing preimplantation genetic diagnosis (PGD) Women who did not undergo embryo transfer due to the freeze-all policy Donor or surrogate cycle

## Age

From **20 years** old to **40 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **152**

Actual sample size reached: **109**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A number of 109 women who met inclusion criteria were explained about the procedure and after signing the written consent form, divided randomly into two groups using random numbers table.

## 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

Ethics Committee of Yazd Reproductive Sciences  
Institute Shahid Sadoughi University

##### Street address

yazd Reproductive Sciences Institute,Bouali  
Ave.,Safaeyeh,Yazd,Iran.

#### City

Yazd

#### Province

Yazd

#### Postal code

8916877391

#### Approval date

2017-05-21, 1396/02/31

#### Ethics committee reference number

IR.SSU.RSI.REC.1396.7

## Health conditions studied

### 1

#### Description of health condition studied

Female infertility

#### ICD-10 code

N97.9

#### ICD-10 code description

Female infertility,unspecified

## Primary outcomes

### 1

#### Description

chemical pregnancy

#### Timepoint

14 days after transfer

#### Method of measurement

BHCG test

### 2

#### Description

clinical pregnancy

#### Timepoint

2 weeks after positive BHCG

#### Method of measurement

Transvaginal sonography

## Secondary outcomes

### 1

#### Description

Fertilization proportion

#### Timepoint

Post oocyte retrieval

#### Method of measurement

The number of fertilized oocytes divided by the total number of oocytes

### 2

#### Description

oocyte recovery rate

#### Timepoint

After oocyte retrieval

### Method of measurement

The number of retrieved oocytes divided by the number of follicles >10 mm in size counted on the day of trigger

### 3

#### Description

oocyte maturity rate

#### Timepoint

After oocyte retrieval

#### Method of measurement

the number of metaphase II (MII) oocytes divided by the number of oocytes retrieved

### 4

#### Description

Fertilization rate

#### Timepoint

After formation of 2PNs

#### Method of measurement

the number of 2PNs divided by the total number of MII oocytes

### 5

#### Description

Implantation rate

#### Timepoint

After detection of gestational sac in ultrasonography

#### Method of measurement

the number of intrauterine gestational sacs observed by transvaginal ultrasonography divided by the total number of transferred embryos

## Intervention groups

### 1

#### Description

Patients in the first intervention group received injection of 450 IU FSH with 5000 IU hCG once on the day of oocyte triggering.

#### Category

Treatment - Drugs

### 2

#### Description

Patients in the second intervention group received injection of 5000 IU hCG once on the day of oocyte triggering.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yazd Reproductive Sciences Institute

### Full name of responsible person

Dr. Abbas Aflatoonian, Professor of Shahid Sadoughi University of Medical Sciences

### Street address

Yazd Reproductive Sciences Institute, Bouali Ave. Safaeiyeh, Yazd

### City

Yazd

### Province

Yazd

### Postal code

8916877391

### Phone

+98 35 3824 7087

### Email

abbas-aflatoonian@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Deputy of Research and Technology, Shahid Sadoughi University

##### Full name of responsible person

Masoud Mirzaei

##### Street address

Bahonar square

##### City

Yazd

##### Province

Yazd

##### Postal code

8916978477

##### Phone

+98 35 3146 2136

##### Email

dvc.research@ssu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Deputy of Research and Technology, Shahid Sadoughi University

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Yazd Reproductive Sciences Institute

**Full name of responsible person**

Pro. Abbas Aflatoonian

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**Yazd Reproductive Sciences Institute, Bouali Ave.  
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**Fax****Email**

abbas\_aflatoonian@yahoo.com

**Web page address****Name of organization / entity**

Yazd Reproductive Sciences Institute

**Full name of responsible person**

Dr.Saeideh Dashti

**Position**

Gynecologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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saeideh\_dashti@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd Reproductive Sciences Institute

**Full name of responsible person**

Prof. Abbas Aflatoonian

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**Yazd Reproductive Sciences Institute; Bouali Ave;  
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**Fax****Email**

abbas\_aflatoonian@yahoo.com

**Web page address****Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All participant data can be shared after making people unidentifiable

**When the data will become available and for how long**

Once data publication

**To whom data/document is available**

people working in academic institutions

**Under which criteria data/document could be used**

Journal who publishes the results

**From where data/document is obtainable**

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. +98353 8247085 Dr. Saeedeh Dashti

**What processes are involved for a request to access data/document**

Two months after the submission of application

**Comments**