

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of Fresh and Frozen Embryo Transfer in GnRH Agonist Triggered patients: A Multicenter Study

#### Protocol summary

##### Study aim

Compare the reproductive outcomes of fresh vs frozen embryo transfer in high responder IVF patients triggered with GnRH $\alpha$

##### Design

Women at risk for OHSS who were stimulated with GnRH antagonist protocol and triggered with GnRH $\alpha$  for oocyte triggering were randomly divided into two groups of either fresh embryo transfer or frozen embryo transfer on the day of oocyte triggering. In this not-blinded, phase 2 clinical trial without control group, randomization was performed using random number table.

##### Settings and conduct

In this multicenter, randomized clinical trial, infertile women at risk of OHSS were recruited at three fertility clinics in Iran; Yazd Research and Clinical Center for Infertility, Yazd Madar Hospital, Mashhad Novin Fertility and Infertility Center. Women were randomized into two groups. Pregnancy outcome were assessed in FET and fresh embryo transfer groups.

##### Participants/Inclusion and exclusion criteria

Patients with OHSS risk at the age between 20-40 yr and having a number of 14-25 follicles  $\geq 12$  mm on the day of trigger and a body mass index  $>18$  and  $<35$  kg/m $^2$  without a previous history of OHSS development.

##### Intervention groups

Group 1: Women were stimulated with GnRH antagonist protocol and triggered with GnRH $\alpha$  for oocyte triggering with fresh embryo transfer Group 2: Women were stimulated with GnRH antagonist protocol and triggered with GnRH $\alpha$  for oocyte triggering with frozen embryo transfer

##### Main outcome variables

The primary outcome parameter was clinical pregnancy and the secondary outcome parameters were chemical pregnancy; live birth; OHSS development; and perinatal outcomes.

#### General information

##### Reason for update

Updating the trial regarding actual sample size, actual recruitment start and end dates

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092224512N4**

Registration date: **2016-10-03, 1395/07/12**

Registration timing: **retrospective**

Last update: **2021-03-24, 1400/01/04**

Update count: **1**

##### Registration date

2016-10-03, 1395/07/12

##### 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

Research Deputy, Shahid Sadoughi Univesity of Medical Science

##### Expected recruitment start date

2014-01-01, 1392/10/11

##### Expected recruitment end date

2015-12-30, 1394/10/09

##### Actual recruitment start date

2014-01-01, 1392/10/11

##### Actual recruitment end date

2015-12-30, 1394/10/09  
**Trial completion date**  
2017-01-30, 1395/11/11  
**Scientific title**  
Comparison of Fresh and Frozen Embryo Transfer in GnRH Agonist Triggered patients: A Multicenter Study

**Public title**  
Pregnancy outcome in Fresh versus Freeze embryo transfer

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 20-40 Hyper responded patients Detection of 14-25 follicles  $\geq$  12 mm on day of trigger BMI  $>$ 18 and  $<$ 35 kg/m<sup>2</sup>

**Exclusion criteria:**

Patients with  $<$ 14 follicles and  $>$  25  $\geq$  12 mm on day of trigger Previous OHSS Endocrine disorders

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **1280**

Actual sample size reached: **280**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this multicenter, randomized clinical trial, 280 infertile women at risk of OHSS were enrolled in the study. All patients were informed about the research design and signed a written consent form. All women were randomly divided into two groups. Randomization was simple, individual using a random number 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**

Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences

**Street address**

Bouali Ave, Safayieh

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Approval date**

2013-12-09, 1392/09/18

**Ethics committee reference number**

IRCT2016092224512N4

**Health conditions studied**

**1**

**Description of health condition studied**

Infertility

**ICD-10 code**

N97

**ICD-10 code description**

inability to achieve a pregnancy sterility, female NOS

**Primary outcomes**

**1**

**Description**

Clinical pregnancy rate

**Timepoint**

7 weeks after embryo transfer

**Method of measurement**

Fetal heart rate in ultra sonography

**Secondary outcomes**

**1**

**Description**

Chemical pregnancy rate

**Timepoint**

14 days after embryo transfer

**Method of measurement**

Beta-hCG using lab kit

**2**

**Description**

livebirth

**Timepoint**

36 weeks after embryo transfer

**Method of measurement**

A live-born baby

**3**

**Description**

Ovarian hyperstimulation syndrome

**Timepoint**

During ovarian stimulation

**Method of measurement**

Measurement of serum anti mullerian hormone level and antral follicle count

#### 4

##### **Description**

Perinatal outcome

##### **Timepoint**

After live birth

##### **Method of measurement**

weight measurement, prematurity status

## **Intervention groups**

#### 1

##### **Description**

Intervention group 1: Freeze of all embryos according to embryo freezing standard protocol at the same cycle.

Thaw all the embryos according to embryo thawing standard protocol and embryo transfer at the next cycle

##### **Category**

Treatment - Other

#### 2

##### **Description**

Intervention group 2: Transfer of 2 fresh embryos at the same cycle Luteal phase support using oral Estradiol Valerat at the dose of 4 mg per day and progesterone (Cyclogest 400 mg) twice daily until observation of fetal heart activity

##### **Category**

Other

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences

###### **Full name of responsible person**

Nasim Tabibnejad

###### **Street address**

Bouali Ave, Safayieh

###### **City**

Yazd

###### **Province**

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###### **Postal code**

8916877391

###### **Phone**

+98 35 3824 7085

###### **Email**

nasimtabib@yahoo.com

#### 2

##### **Recruitment center**

###### **Name of recruitment center**

Madar Hospital

###### **Full name of responsible person**

Abbas Aflatoonian

###### **Street address**

Mahdieh Square

###### **City**

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###### **Email**

info@madarhospital.com

#### 3

##### **Recruitment center**

###### **Name of recruitment center**

Novin Infertility Center

###### **Full name of responsible person**

Mahnaz Mansouri

###### **Street address**

8th Kowsar Street, Kowsar BLVD

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

###### **Postal code**

5138833888

###### **Phone**

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###### **Email**

novinivf@gmail.com

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Research Deputy, Shahid Sadoughi University of Medical Sciences

###### **Full name of responsible person**

Amirhooshang Mehrparvar

###### **Street address**

Bahonar Square

###### **City**

Yazd

###### **Province**

Yazd

###### **Postal code**

8916978477

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###### **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**  
Research Deputy, Shahid Sadoughi University of Medical Sciences  
**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**  
Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences  
**Full name of responsible person**  
Nasim Tabibnejad  
**Position**  
PhD student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Reproductive Biology  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences  
**Full name of responsible person**  
Abbas aflatoonian  
**Position**  
Gynecologist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
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abbas-aflatoonian@ssu.ac.ir  
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## Person responsible for updating data

### Contact

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Research and Clinical center for Infertility, Shahid Sadoughi University of medical Sciences  
**Full name of responsible person**  
Nasim Tabibnejad  
**Position**  
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**Other areas of specialty/work**  
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**Web page address**

## 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 sets are to be shared

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

2 months after the result publication

**To whom data/document is available**

A journal in which the results are published

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

Submission of an official application via the agent that is legally in charge

**From where data/document is obtainable**

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. 983538247085 abbas\_afatoonian@yahoo.com

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

2 months after application

**Comments**