

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The clinical trial to compare the effect of fentanyl, remifentanyl and alfentanil on hemodynamic parameters and pregnancy outcome in patients undergoing ovarian puncture

#### Protocol summary

##### Summary

The aim of present study is to evaluate effects of fentanyl, alfentanil and remifentanyl on hemodynamic parameters, recovery time and pregnancy outcome in patients undergoing anesthesia for transvaginal oocyte retrieval. The inclusion criteria include: age under 40 years and fresh embryo transfer. The exclusion criteria include: azoospermia; follicle stimulating hormone greater than 10; endocrine disorders; poor ovarian response and chronic use of drugs. The present study is a randomized, double blind, uncontrolled clinical trial on infertile patients. All patients will be treated with gonadotropin releasing hormone agonist. Two hundred forty patients will be included in the present study. After final oocyte maturation, ultrasound guided oocyte retrieval will be performed under general anesthesia. Induction of general anesthesia in fentanyl group will be conducted with 1.5 micrograms fentanyl, 40 milligrams lidocaine and 2 milligrams propofol. The other two groups alfentanil and remifentanyl will be anesthetized with 15 micrograms alfentanil and 1.5 micrograms remifentanyl. Other drugs will be the same between groups. Postoperative vital signs, nausea and vomiting, shivering, cough, pain severity measured on a visual analog scale and time of consciousness, will be monitored. Biochemical and clinical pregnancy rate and the number of gestational sac will be reported.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201410258677N4**  
Registration date: **2015-01-21, 1393/11/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-21, 1393/11/01

##### Registrant information

###### Name

Farnoush Farzi

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1322 5624

###### Email address

farnoush\_farzi@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2014-11-22, 1393/09/01

##### Expected recruitment end date

2016-03-05, 1394/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The clinical trial to compare the effect of fentanyl, remifentanyl and alfentanil on hemodynamic parameters and pregnancy outcome in patients undergoing ovarian puncture

##### Public title

The effect of type of opioid drugs on hemodynamic

parameters and pregnancy outcome in patients undergoing ovarian puncture

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Age under 40 years; Fresh embryo transfer cycles. Exclusion criteria: Azoospermia; Follicle stimulating hormone level greater than 10; Polycystic ovarian syndrome; Endocrine disorders; Poor responders; Unexplained infertility; Cardiopulmonary disease; Chronic use of drugs; Allergy; Difficult embryo transfers; Bloody catheter.

### **Age**

From **19 years** old to **39 years** old

### **Gender**

Female

### **Phase**

3

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

*No information*

### **Sample size**

Target sample size: **240**

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

Randomized

### **Randomization description**

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

Double 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 Guilan University of Medical Sciences

##### **Street address**

Research Deputy of Guilan University of Medical Sciences, Shahid Beheshti Boulevard

##### **City**

Rasht

##### **Postal code**

#### **Approval date**

2014-11-17, 1393/08/26

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

1930382808

## **Health conditions studied**

### 1

#### **Description of health condition studied**

In vitro fertilization patients

#### **ICD-10 code**

N98.2

#### **ICD-10 code description**

Complications of attempted introduction of fertilized ovum following in vitro fertilization

## **Primary outcomes**

### 1

#### **Description**

Blood pressure

#### **Timepoint**

Every three minutes

#### **Method of measurement**

Non-invasive

### 2

#### **Description**

Heart rate

#### **Timepoint**

Continuous monitoring

#### **Method of measurement**

Electrocardiogram - Pulse oximeter

### 3

#### **Description**

Pregnancy outcome

#### **Timepoint**

Two weeks and three months after embryo transfer

#### **Method of measurement**

Human chorionic gonadotropin test - Ultrasound

### 4

#### **Description**

Recovery time

#### **Timepoint**

Since the arrival of the patient to the recovery room until respond to voice commands

#### **Method of measurement**

Postanesthesia discharge scoring system

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

In the first intervention group, induction of general anesthesia will be performed with administration of 1.5 micrograms fentanyl, 40 milligrams lidocaine and 2 milligrams propofol

#### **Category**

Treatment - Drugs

## 2

### Description

In the second intervention group, induction of general anesthesia will be performed with administration of 15 micrograms alfentanil, 40 milligrams lidokain and 2 milligrams propofol

### Category

Treatment - Drugs

## 3

### Description

In the third intervention group, induction of general anesthesia will be performed with administration of 1.5 micrograms remifentanil, 40 milligrams lidokain and 2 milligrams propofol

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mehr Medical Institute

##### Full name of responsible person

Dr Farnoush Farzi

##### Street address

Mehr Medical Institute, Ershad Street, Shahid Ansari Boulevard

##### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mehr Medical Institute

##### Full name of responsible person

Dr Farnoush Farzi

##### Street address

Mehr Medical Institute, Ershad Street, Shahid Ansari Boulevard

##### City

Rasht

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mehr Medical 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

Al-Zahra Hospital, Guilan University of Medical Sciences

#### Full name of responsible person

Dr Farnoush Farzi

#### Position

Anesthesiologist; Associate Professor

#### Other areas of specialty/work

#### Street address

Al-Zahra Hospital, Namjoo Street

#### City

Rasht

#### Postal code

4144654839

#### Phone

00981333322021

#### Fax

+98 13 3332 5624

#### Email

farnoush\_farzi@yahoo.com;  
farnoush\_farzi@gums.ac.ir

#### Web page address

www.mehrinstitute.org

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Al-Zahra Hospital, Guilan University of Medical Sciences

#### Full name of responsible person

Dr Farnoush Farzi

#### Position

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#### Other areas of specialty/work

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## Person responsible for updating data

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**Web page 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*