

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

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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

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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

Anesthesiologist; Associate Professor

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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