

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of anesthesia by Remifentanil with or without Propofol for Transvaginal Ultrasonography Oocyte Retrieval (TUGOR) on pregnancy and anesthesia outcomes in patients candidate for in vitro fertilization

Protocol summary

Summary

In current single center, double-blinded randomized clinical trial, 180 women aged between 18-40, candidate for oocytes collection by vaginal ultrasonography will enroll the study and randomly assigned to study groups. Randomization has been performed using online randomization method and sealed envelope. Patients with sensitivity to anesthesia drugs and chronic diseases will be excluded. After hormonal therapy by gynecologist to induce ovulation, oocyte collection procedure will be performed through vagina with the guide of ultrasonography. All patients will receive 0.3 mg/kg midazolam and 0.1 µg/kg bullous remifentanil. In terms of maintenance anesthesia drugs, patients will be randomly assign to two groups: study group (90 patients) will receive remifentanil infusion during procedure with dose of 0.25 µg/kg/min and control group (90 patients) will receive 1 µg/kg/min remifentanil combined with 50-150 µg/kg/min Propofol infusion. Patients' vital signs will be checked and recorded during operation and after that, with 5 minute intervals. In addition, procedure duration and anesthesia duration will be record. Overall infused remifentanil and propofol dosage and probable side effects will be examined and recorded during recovery phase. Subsequently, retrieved oocytes numbers and successful fertilization and pregnancy rate will be recorded. An anesthesiologist will manage the patients' anesthesia and another anesthesiologist and a medical student, who are blind to patients group, will record different variables indicated in questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611177013N15**
Registration date: **2016-12-24, 1395/10/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-24, 1395/10/04

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 3806

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atashkhoei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-12-01, 1395/09/11

Expected recruitment end date

2017-02-01, 1395/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthesia by Remifentanil with or without Propofol for Transvaginal Ultrasonography

Oocyte Retrieval (TUGOR) on pregnancy and anesthesia outcomes in patients candidate for in vitro fertilization

Public title

Remifentanyl infusion effect on oocyte retrieval

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Class I and II in American society of anesthesiology classification; aged between 18-40 years old. Exclusion criteria: Body mass index (BMI) more than 30; sensitivity to anesthesia drugs will be used in study; history of cardiac, endocrine, hepatic, renal and pulmonary diseases; chronic use of opioid drugs or alcohol.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization has been performed using online randomization method and sealed envelope.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Tabriz university of medical sciences, Daneshgah square

City

Tabriz

Postal code**Approval date**

2016-09-26, 1395/07/05

Ethics committee reference number

IR.TBZMED.REC.1395.691

Health conditions studied**1****Description of health condition studied**

Anesthetics complication and efficacy

ICD-10 code

O 29.

ICD-10 code description

Complications of anaesthesia during pregnancy

Primary outcomes**1****Description**

clinical pregnancy rate

Timepoint

3 weeks after embryo transfer

Method of measurement

ultrasonography study

2**Description**

rate of transferred oocytes

Timepoint

after operation

Method of measurement

will be counted using microscope

3**Description**

Number of collected oocytes

Timepoint

during operation

Method of measurement

will be counted using microscope

4**Description**

laboratory pregnancy rate

Timepoint

14 days after embryo transfer

Method of measurement

B-hCG measurement

5**Description**

rate of fertilized oocytes

Timepoint

after operation

Method of measurement

will be counted using microscope

Secondary outcomes

1

Description

Postoperative vertigo

Timepoint

each 5 minutes during first hour after operation

Method of measurement

physical examination

2

Description

Postoperative hypotension

Timepoint

each 5 minutes during first hour after operation

Method of measurement

physical examination

3

Description

Postoperative nausea and vomiting

Timepoint

each 5 minutes during first hour after operation

Method of measurement

physical examination

4

Description

Postoperative drowsiness

Timepoint

each 5 minutes during first hour after operation

Method of measurement

physical examination

5

Description

perioperative hypotension

Timepoint

each 5 minutes during operation

Method of measurement

physical examination

6

Description

perioperative tachycardia

Timepoint

each 5 minutes during operation

Method of measurement

physical examination

7

Description

perioperative bradycardia

Timepoint

each 5 minutes during operation

Method of measurement

physical examination

8

Description

perioperative respiratory suppression

Timepoint

each 5 minutes during operation

Method of measurement

physical examination

9

Description

perioperative pain

Timepoint

each 5 minutes during operation

Method of measurement

physical examination

Intervention groups

1

Description

Intervention group: 0.25 µg/kg/min remifentanyl will be infused during operation.

Category

Treatment - Drugs

2

Description

Control group: 1 µg/kg/min remifentanyl combined with 50-150 µg/kg/min propofol will be infused during operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Women's Hospital

Full name of responsible person

Dr. Simin Atashkhoyi

Street address

Baghshomal crossroad, North artesh street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of medical sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of
medical sciences, Daneshgah square

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of medical
sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

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Other areas of specialty/work

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Web page address

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