

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of hemodynamic changes between two methods of sedation with midazolam - fentanyl and propofol - fentanyl in patients undergoing ovarian puncture surgery

Protocol summary

Summary

The purpose of this double-blind clinical trial study is to comparison of hemodynamic changes between sedation by midazolam_fentanyl versus propofol_fentanyl in patients who undergoing ovarian puncture procedure in Imam Khomeini hospital during 2015-2016. The inclusion criteria include: infertile women between 21 -39 years; normal blood pressure; class I and II ASA; lack of sensitivity to propofol, undergoing puncture elective surgery. Exclusion criteria include: unwillingness to participate in the study; puncture procedure took more than 10 minutes. 56 patients will be randomized into two groups in blocks of 4: Group A (28) patients (propofol-fentanyl) and B (28) patients (midazolam-fentanyl) will be considered. Patients in group A, Will be sedate by propofol 1mg/kg, fentanyl 1 micrograms/kg and patients in group B will be sedate by midazolam 0.05mg/kg, fentanyl 1 micrograms/kg while receiving oxygen and N2O 4lit/min via bag- mask ventilation. After securing the sedation, surgery will begin. The systolic and diastolic blood pressure, heart rate, respiratory rate and O2 saturation before induction, then 3, 5 and 10 minutes after induction will be evaluated. Then, the hemodynamics parameters will be evaluated and will be recorded when the patients are delivered to and left the recovery Ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092814802N1**

Registration date: **2016-05-25, 1395/03/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name

Sara Adarvishi

Name of organization / entity

Ahvaz Jondishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

vice-chancellor for research and technology of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic changes between two methods of sedation with midazolam - fentanyl and propofol - fentanyl in patients undergoing ovarian puncture surgery

Public title

Changes in vital signs in two ways of anesthesia with

midazolam- fentanyl and propofol- fentanyl in patients with infertility surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: infertile women between 21 -39 years; normal blood pressure; class I and II ASA; lack of sensitivity to propofol, undergoing puncture elective surgery. Exclusion criteria: unwillingness to participate in the study; puncture procedure took more than 10 minutes.

Age

From **21 years** old to **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

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 ahvaz University of Medical Sciences

Street address

Ethics Committee, vice-chancellor for research and technology, Jundishapur University of Medical Sciences, Golestan street, Ahvaz

City

ahvaz

Postal code

6135715794

Approval date

2016-02-10, 1394/11/21

Ethics committee reference number

Ajums.REC.1394.561

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N99.9

ICD-10 code description

Other disorders of the genitourinary system

Primary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

Before induction, then 3, 5 and 10 minutes after induction

Method of measurement

Portable analog pressure gauge

2

Description

heart rate

Timepoint

Before induction, then 3, 5 and 10 minutes after induction

Method of measurement

monitoring

3

Description

respiratory rate

Timepoint

Before induction, then 3, 5 and 10 minutes after induction

Method of measurement

Observation chest in a minute

4

Description

saturation of oxygen

Timepoint

Before induction, then 3, 5 and 10 minutes after induction

Method of measurement

Pulse oximeter probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients in group A Will be sedate by propofol 1mg/kg, fentanyl 1 micrograms/kg while receiving oxygen and N2O 4lit/min via bag- mask

ventilation. After securing the sedation, surgery will begin. The systolic and diastolic blood pressure, heart rate, respiratory rate and O2 saturation before induction, then 3, 5 and 10 minutes after induction will be evaluated.

Category

Treatment - Drugs

2**Description**

Intervention group 2: will be sedate by midazolam 0.05mg/kg, fentanyl 1 micrograms/kg while receiving oxygen and N2O 4lit/min via bag- mask ventilation. After securing the sedation, surgery will begin. The systolic and diastolic blood pressure, heart rate, respiratory rate and O2 saturation before induction, then 3, 5 and 10 minutes after induction will be evaluated.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

imam khomeini hospital of ahvaz

Full name of responsible person

saeed haji taheri

Street address

imam khomeini hospital of ahvaz, azadegan street, ahvaz, khozestan.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

vice-chancellor for research and technology of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

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Ahvaz Jundishapur University of Medical Sciences, vice-chancellor for research and technology, Golestan street, Ahvaz, Khozestan

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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 and technology of Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

MSc student of nursing education

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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