# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jul 2026

## A comparison of Propofol with ketofol (a Ketamine-Propofol combination) for sedation during hysteroscopy in patient in IVF operation room

## Protocol summary

**Summary**
In a double-blind clinical trial study involving women referred to Imam Khomeini Hospital, Ahwaz, Iran for hysteroscopy are randomly divided into two groups of 20. Induction of anesthesia in a group with propofol and the other group receive ketofol (ketamine and propofol). Vital signs including systolic blood pressure, heart rate, expiratory carbon dioxide levels, the depth of anesthesia and the incidence of apnea before and after drug administration are measured and the incidence of patient's complications in the recovery and the recovery time are compared between groups.

## General information

**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT201105176510N1**
Registration date: **2012-02-14, 1390/11/25**
Registration timing: **retrospective**

Last update:
Update count: **0**
**Registration date**
2012-02-14, 1390/11/25

**Registrant information**
**Name**
Seyed Amin Mousavian Roshanzamir
**Name of organization / entity**
Joundishapour Ahwaz university of medical sciences
**Country**
Iran (Islamic Republic of)
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+98 61 1332 3834
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**Recruitment status**
**Recruitment complete**
**Funding source**
Ahwaz Jondishapour University of Medical Sciences

**Expected recruitment start date**
2011-09-23, 1390/07/01
**Expected recruitment end date**
2011-10-22, 1390/07/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
A comparison of Propofol with ketofol (a Ketamine-Propofol combination) for sedation during hysteroscopy in patient in IVF operation room

**Public title**
A comparison of Propofol with ketofol (a Ketamine-Propofol combination) for sedation during hysteroscopy in patient in IVF operation room
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
Inclusion criteria: age under 40y, ASA class 1&2, no cardiovascular risk factor, no history of reaction to egg or soy bean & Ketamine or propofol, no psychiatric history, no history of airway difficulty. Exclusion criteria: airway difficulty like difficult ventilation, change of hysteroscopy to open surgery or complicated hysteroscopy.
**Age**
From **15 years** old to **40 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Single
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Jondishapour University of Medical Sciences
**Street address**
Golestan Boulevard
**City**
Ahwaz
**Postal code**
12335645
**Approval date**
2011-07-27, 1390/05/05
**Ethics committee reference number**
Eth196

## Health conditions studied

### 1

**Description of health condition studied**
Parenteral anaesthetics
**ICD-10 code**
Y48.1
**ICD-10 code description**
Parenteral anaesthetics

## Primary outcomes

### 1

**Description**
Depth of anesthesia
**Timepoint**
5 minute after induction of anesthesia
**Method of measurement**
with Bispecteral Index Score device

## Secondary outcomes

### 1

**Description**
Incidence of apnea
**Timepoint**
in time of anesthesia
**Method of measurement**
observation of anesthesiologist

### 2

**Description**
Incidence of nausea & vomiting
**Timepoint**
in time of anesthesia & recovery
**Method of measurement**
observation of anesthesiologist

### 3

**Description**
Systolic blood pressure
**Timepoint**
before & 5 minute after induction of anesthesia
**Method of measurement**
automatic blood pressure device

### 4

**Description**
Pulse rate
**Timepoint**
before & 5 minute after induction of anesthesia
**Method of measurement**
ECG monitoring device

### 5

**Description**
psychiatric side effect
**Timepoint**
recovery period
**Method of measurement**
observation of anesthesiologist

## Intervention groups

### 1

**Description**
Intervention group: combination of ketamine and propofol to 5mg/kg of each drugs that inject to patients to 1 mg/kg of propofol.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: combination of propofol with sterile water to 5mg/kg of propofol that inject to patients to 1 mg/kg of propofol.
**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
IVF ward, Ahwaz Imam Khomeini Hospital
**Full name of responsible person**
Khoshnud, Saeideh
**Street address**
Imam Khomeini Hospital
**City**
Ahwaz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Ahwaz Jondi Shapur University of medical sciences
**Full name of responsible person**
Feghi Mostafa
**Street address**
Golestan Boulevard
**City**
Ahwaz
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Ahwaz Jondi Shapur 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**
Ahwaz Jondi Shapour University of medical sciences
**Full name of responsible person**
Seyed Amin Mousavian Roshan Zamir
**Position**
Resident of Anesthesiology
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*