Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Phone

+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
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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