

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Compare the Ketofol and Sodium thiopental in General anesthesia patients undergoing dilatation and curettage in Alavi hospital from 2016

#### Protocol summary

##### Summary

This study is a double-blind randomized clinical trial, on 80 patients, with the aim of survey Compare the Ketofol and Sodium thiopental in General anesthesia patients undergoing dilatation and curettage in Alavi hospital from 2016 will be done. Inclusion criteria including Vaginal bleeding, patients suspected to have an abortion, Patients candidate of uterine curettage, consent to participate in the study and exclusion criteria included contraindication to uterine curettage, sensitivity to Ketofol and Sodium thiopental, conversion. Patients randomly with using random numbers table will be divided into two groups of 40 Patients and Intraoperative the first group Ketofol(Half milligrams per weight ketamine and One mg per Kg of propofol) and to second group 3 mg per Kg Sodium thiopental will be injected. Intraoperative, unaware questioner will be survey change of hemodynamic and respiratory disorders as the primary outcome and patient satisfaction with anesthesia and surgeon satisfaction after surgery will be recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017031923559N9**

Registration date: **2017-04-24, 1396/02/04**

Registration timing: **na**

Last update:

Update count: **0**

##### Registration date

2017-04-24, 1396/02/04

##### Registrant information

###### Name

Somaieh Matin

###### Name of organization / entity

Ardabil University of Medicine Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3373 3011

###### Email address

s.matin@arums.ac.ir

###### Recruitment status

**Not enough for processing**

###### Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

###### Expected recruitment start date

2017-04-21, 1396/02/01

###### Expected recruitment end date

empty

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Compare the Ketofol and Sodium thiopental in General anesthesia patients undergoing dilatation and curettage in Alavi hospital from 2016

###### Public title

Compare the Ketofol and Sodium thiopental in General anesthesia patients undergoing dilatation and curettage

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Vaginal bleeding; patients suspected to have an abortion; Patients candidate of uterine curettage; consent to participate in the study. Exclusion criteria: contraindication to uterine curettage; sensitivity to Ketofol and Sodium thiopental

###### Age

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study divided patients into two groups and will be used by Table of random numbers. Classification of patients will be done by operator and anesthesia technician that injects the drug is not aware of the type of drugs.

**Secondary Ids**

empty

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

Ethics committee of Ardabil University of Medical Sciences

**Street address**

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

**City**

Ardabil

**Postal code**

53141-56198

**Approval date**

2016-10-03, 1395/07/12

**Ethics committee reference number**

IR.ARUMS.REC.1395.55

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

Surgical abortion

**ICD-10 code**

O08.1

**ICD-10 code description**

Complete or unspecified, complicated by delayed or excessive haemorrhage

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

Apnea

**Timepoint**

Intraoperative

**Method of measurement**

Based on the patient's respiratory status

**Secondary outcomes****1****Description**

Patient satisfaction of anesthesia

**Timepoint**

Intraoperative

**Method of measurement**

question of patient

**2****Description**

Decreased oxygen saturation

**Timepoint**

Intraoperative

**Method of measurement**

According to pulse oximetry

**Intervention groups****1****Description**

The first group injected Ketofol that contains a half milligrams per kilogram of ketamine and 1 mg per kg body weight propofol before the surgery. The second group of three milligrams per kilogram of sodium thiopental injected before the surgery.

**Category**

Treatment - Drugs

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

Imam Khomeini Hospital

**Full name of responsible person**

Mahzad Yousefian MD

**Street address**

Imam Khomeini Hospital, Shahid Ghafour Jeddi St, Ardabil

**City**

Ardabil

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Ardabil University of Medical Sciences

**Full name of responsible person**

Shahram Habibzadeh M.D. Deputy of Research and Technology

**Street address**

Vice Chancellor for Research and Technology, University of Medical Sciences, Ardabil.

**City**

Ardabil

**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, Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Mahzad Yousefian

**Position**

Assistant Professor, Department of Anesthesiology

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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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*