

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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**

Imam Khomeini Hospital, Shahid Ghafour Jeddi St, Ardabil

City

Ardabil

Postal code

5618985991

Phone

+98 45 3225 1688

Fax

+98 45 3225 1688

Email

mahzad_yousefian@yahoo.com

Web page address

Person responsible for scientific 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**

Imam Khomeini Hospital, Shahid Ghafour Jeddi St, Ardabil

City

Ardabil

Postal code

5618985991

Phone

+98 45 3225 1688

Fax

+98 45 3225 1688

Email

mahzad_yousefian@yahoo.com

Web page address

Person responsible for updating data

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**

Imam Khomeini Hospital, Shahid Ghafour Jeddi St, Ardabil

City

Ardabil

Postal code

5618985991

Phone

+98 45 3225 1688

Fax

+98 45 3325 1688

Email

mahzad_yousefian@yahoo.com

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