

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of the effect of ketofol with dexmedetomidine on anesthesia in patients undergoing dilatation and curettage

#### Protocol summary

##### Study aim

Comparison of the effect of ketofol with dexmedetomidine on anesthesia in patients undergoing dilatation and curettage

##### Design

The study will be a controlled intervention that is non-random and blinded. Sample size included 150 patients with dilatation and curettage.

##### Settings and conduct

The study will be performed on patients who are candidates for dilatation and curettage who will be referred to Alavi Hospital in Ardabil. The patients will be divided into 3 groups described and will be monitored in all three groups after the patient enters the operating room. Then an appropriate venous route is established and primary hydration will be performed. Oxygen will be provided with a mask for all patients. Then, any hemodynamic changes or respiratory disorders including apnea or hypoventilation and suction loss and need for respiratory support and recovery time will be recorded in all three groups. Randomization and blinding were not observed in the study

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 16 years of age, candidates for dilatation and curettage with grade 1 and 2 ASA, and consent to participate in the study. Exclusion criteria: A history of allergy to propofol and other injectable anesthetics, drug abusers, alcohol and psychotropic drugs, hypertension.

##### Intervention groups

The first group received ketofol at the ratio of ketamine (0.5 mg / kg) to propofol (1 mg / kg), the second group dexmedetomidine at a dose of 1 mg / kg / stat for 10 minutes, then 1 µg / kg / h and the third group received propofol at a dose of 1 mg / kg. 1 kg and then isoflurane 1% will be prescribed for patients

##### Main outcome variables

The incidence of apnea during anesthesia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191022045203N1**

Registration date: **2019-11-14, 1398/08/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-14, 1398/08/23**

Update count: **0**

##### Registration date

2019-11-14, 1398/08/23

##### Registrant information

##### Name

Mahzad Yousefian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3323 0739

##### Email address

n.hagshenas@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-11-21, 1398/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of ketofol with dexmedetomidine on anesthesia in patients undergoing dilatation and curettage

#### Public title

Comparison of the effect of ketofol with dexmedetomidine on anesthesia in patients undergoing dilatation and curettage

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Ages over 16 years and less than 65 years Candidate of dilatation and curettage with grade 1 and 2 ASA Participation in the study

##### Exclusion criteria:

Under 16 years There is an underlying disease like cancer

#### Age

From **16 years** old to **65 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **150**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not 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 Ardabil University of Medical Sciences

###### Street address

No. 1, Daneshgah Ave

###### City

Ardabil

###### Province

Ardabil

###### Postal code

5613874758

##### Approval date

2019-08-19, 1398/05/28

#### Ethics committee reference number

IR.ARUMS.REC.1398.266

### Health conditions studied

#### 1

##### Description of health condition studied

dilatation and curettage

##### ICD-10 code

O03.9

##### ICD-10 code description

Complete or unspecified spontaneous abortion without complication

### Primary outcomes

#### 1

##### Description

The main outcome in the study of apnea or hypoventilation during anesthesia is.

##### Timepoint

The patient will be monitored continuously during anesthesia.

##### Method of measurement

Given the pulse oximeter

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group1: The first group will be administered ketofol at a ratio of ketamine (0.5 mg / kg) to propofol (1 mg / kg) for 10 minutes, then 1 µg / kg / h and then 1% isoflurane.

##### Category

Treatment - Drugs

#### 2

##### Description

Intervention group2: Intervention group: Dexmedetomidine will be administered to patients in the second group at a dose of 1 mg / kg / stat for 10 minutes, then 1 µg / kg / h and then 1% isoflurane.

##### Category

Treatment - Drugs

#### 3

##### Description

Control group: Propofol 1 mg / kg and then isoflurane 1% will be given to patients.

##### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Alavi Hospital

**Full name of responsible person**

Negin Haghshenas

**Street address**

No. 1 , Moallem Ave

**City**

Ardabil

**Province**

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**Postal code**

5613843568

**Phone**

+98 45 3323 0739

**Email**

meisamfooladi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Parvaneh Naftchi

**Street address**

No. 1, Faneshgah Ave

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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**

Ardabil University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## 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

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

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Ardabil University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The questionnaires will be made available anonymously and with a file number.

**When the data will become available and for how long**

After completing the study

**To whom data/document is available**

اساتید دانشگاه ها

**Under which criteria data/document could be used**

In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.

**From where data/document is obtainable**

Contact Dr. Mahzad Yousefian.

**What processes are involved for a request to access data/document**

En Information is available after contacting Dr. Mahzad Yousefian and University approval

**Comments**