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)

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+98 45 3323 0739

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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvaneh Naftchi
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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 updating data

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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