Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Propofol and Ketamine Combination (Ketofol) and Propofol and Fentanyl combination (Fenofol) on sedation and analgesia in patients undergoing lumpectomy

Protocol summary

Study aim
Determine and compare of Propofol - Ketamine Combinations and Propofol - Fentanyl combination for procedural sedation and analgesia in lumpectomy

Design
This study is a double-blind, randomized clinical trial, with a parallel group design and includes 64 people. The patients will be randomly divided into 2 groups (each consists of 32 members).

Settings and conduct
The present study was performed on 64 patients with breast mass referred to Isfahan Seyyed Al-Shohada Hospital during 2016-17. The patients aged 15-70 years old with physical status III on ASA class were choosed as candidates for lumpectomy.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the patients at the age of 15 to 70 years old; suffering from breast cancer. Exclusion criteria: Allergy to the study drug; severe cardiovascular disease; severe pulmonary disease.

Intervention groups
Intervention group 1 received Ketamine and Propofol combination (Ketofol). Intervention group 2 received Fentanil and Propofol combination (Fenofol).

Main outcome variables
sedation; analgesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160812029310N4**
Registration date: **2018-07-01, 1397/04/10**
Registration timing: **retrospective**

Last update: **2018-07-01, 1397/04/10**
Update count: **0**

Registration date
2018-07-01, 1397/04/10

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3224 7233

Email address
b.nazemroaya@khuisf.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-02-28, 1395/12/10

Expected recruitment end date
2017-08-01, 1396/05/10

Actual recruitment start date
2017-10-23, 1396/08/01

Actual recruitment end date
2018-05-15, 1397/02/25

Trial completion date
empty

Scientific title
Comparison of Propofol and Ketamine Combination (Ketofol) and Propofol and Fentanyl combination (Fenofol) on sedation and analgesia in patients undergoing lumpectomy

Public title
Effect of Ketofol and Fenofol on sedation and analgesia

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:

The patients at the age of 15-70 years old ASAIII With breast cancer ASA I,II candidates for lumpectomy

Exclusion criteria:

Difficult airway management mental disorder allergy to drugs head Injury Severe cardiovascular disease Severe pulmonary disease history of Epilepsy or Seizure

Age

From **15 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to the two groups of Fenofol and Ketofol using random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

All drugs are prepared and placed at the same volume and homogeneously into the syringes by the investigator. The hemodynamic changes (after the administration of each drug) are monitored and recorded. Moreover, the Participant, Care provider, Outcome assessor, and Data analyser are not aware of the drug type and the investigator will decipher the codes after data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jarib street, Azadi square, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2017-06-28, 1396/04/07

Ethics committee reference number

Ir.mui.rec1396.3.220

Health conditions studied

1

Description of health condition studied

sedation

ICD-10 code

ICD-10 code description

2

Description of health condition studied

analgesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean arterial pressure

Timepoint

Before and after the intervention, one, three, five, ten minutes after induction of anesthesia and then at 60 and 120 minutes

Method of measurement

Non invasive blood pressure Automated

2

Description

Heart rate

Timepoint

Before and after the intervention, 1, 3, 5, 10 minutes after induction of anesthesia and then at 60 and 120 minutes

Method of measurement

Pulse oximetry device

3

Description

Arterial oxygen saturation

Timepoint

Before and after the intervention, 1, 3, 5, 10 minutes after induction of anesthesia and then at 60 and 120 minutes

Method of measurement

Pulse oximetry device

Secondary outcomes

1

Description
Intensity of pain
Timepoint
At times 1, 3, 5, 10 minutes after induction of anesthesia and then at 60 and 120 minutes after induction of anesthesia
Method of measurement
Using criterion VAS

Intervention groups

1

Description
Intervention group 1: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and attached standard monitoring devices including pulsoximetry, capnography, and electrocardiogram. Baseline vital signs are recorded and the drugs are administered firstly through bolus injection and after that through continuous infusion. In this group, propofol (manufactured by B.Braun company Germany) at the dose of 1 mg/kg plus ketamine (manufactured by Rotexmedica Germany) at the dose of 1 mg/kg are infused during 10 minutes. Mean blood pressure, heart rate and oxygen saturation are recorded 1, 3, 5, 10, 60 and 120 minutes after induction.
Category
Treatment - Drugs

2

Description
Intervention group 2: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and attached standard monitoring devices including pulsoximetry, capnography, and electrocardiogram. Baseline vital signs are recorded and the drugs are administered firstly through bolus injection and after that through continuous infusion. In this group, propofol (manufactured by B.Braun company Germany) at the dose of 1 mg/kg plus Fentanyl (manufactured by Rotexmedica Germany) at the dose of 1mcg/kg are infused during 10 minutes. Mean blood pressure, heart rate and oxygen saturation during 1, 3, 5, 10 minutes after induction and at 60 and 120 minutes are recorded.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed Alshohada hospital
Full name of responsible person
Behzad Nazemroaya
Street address
Seyed Alshohada hospital, Tohid boulivard, , Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3236 7442
Email
behzad_nazem@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghyegh Haghjoo
Street address
Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
behzadnazemroaya797@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Behzad Nazemroaya
Position

Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ostandari
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3224 7233
Email
behzad_nazem@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Behzad Nazemroaya
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ostandari
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3224 7233
Email
behzad_nazem@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Behzad Nazemroaya
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ostandari
City
Isfahan
Province
Isfehan
Postal code
8146713543
Phone
+98 31 3224 7233
Email
behzad_nazem@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only registered symptoms can be published without mentioning the names of the participants.
When the data will become available and for how long
"Starting the access period 6 months after printing results"
To whom data/document is available
Only available to scholars working in academia and academia
Under which criteria data/document could be used
Written request via email and university approval
From where data/document is obtainable
By contacting corresponding author
What processes are involved for a request to access data/document
After the email is received by the applicant, it takes one week to agree The university will be obtained and then will be notified to the requestor. Maximum of this process takes ten days.
Comments