

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)

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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

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Province

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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 pulse oximetry, 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 pulse oximetry, 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

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Seyed Alshohada hospital, Tohid boulevard, , Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghyegh Haghjoo

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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

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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