Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of effects of ephedrine,lidocaine and ketamine with placebo on injection pain and hypotention & bradycardia due to propofol injection in patient under general anesthesia

Protocol summary

Summary

The purpose of this study is selection of the best drug among three available drugs: ephedrine, lidocaine and ketamine with a low dose to reduce injection pain and hypotension and bradycardia due to propofol injection. This randomized double-blinded placebo-controlled clinical trial study perform on 140 patients 20-40 years in ASA class I, who are candidate for elective surgery and anesthesia induction with propofol and the first experience of anesthesia. Patients randomly allocate to receive ephedrine 0.1mg/kg (Group E, n = 35) or lidocaine2% (group L, n=35) or ketamine0.1mg/kg (group K, n=35) or normal saline (group N, n=35) in volumes of 2cc, intravenously 30 second before propofol injection. During slow injection of propofol, pain and its severity is assessed with 4 points scale (0=no pain , 1=mild pain with frown, 2=moderate pain with frown and whine , 3=sever pain with withdrawal movement of hand and squeal).Then 1.5- 2 cc fentanyl and 0.5 mg/kg atracurium is injected and after 3 min ventilation, trachea is intubated.systolic, diastolic and mean blood pressure and heart rate are measured and recorded before induction, just before intubation and after tracheal intubation.finally we analyze the collected data with using statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102055764N1**
Registration date: **2011-04-12, 1390/01/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-12, 1390/01/23

Registrant information

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Vida Ayatollahi
Name of organization / entity
Shahid Sadughi University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2009-12-22, 1388/10/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of effects of ephedrine,lidocaine and ketamine with placebo on injection pain and hypotention & bradycardia due to propofol injection in patient under general anesthesia

Public title

Which drug is better for reducing injection pain and hypotention & bradycardia due to propofol injection

Purpose
Prevention
Inclusion/Exclusion criteria
inclusion criteria: ; All of patients in ASA class I, who are candidated for elective surgery and anesthesia with propofol and this anesthesia is the first experience for them; exclusion criteria: ;Any patients that has unpredictable complications during information recording to (such asbronchospasms , ...) pain at the Injection site before or during the study drugs injection (before injection of propofol) Previous sensitivity to study drugs anxiety and lack of cooperation;
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Medical Sciences and Health Services Shaid Sadoughi university
Street address
Central Organization of Medical Sciences and Health Services Shahid Sadoughi, Dr Bahonar Square
City
Yazd
Postal code
8916978477
Approval date
2009-06-07, 1388/03/17
Ethics committee reference number
17/1/22456/پ

Health conditions studied

1

Description of health condition studied
propofol injection pain
ICD-10 code
y48.2
ICD-10 code description
Drugs, medicaments and biological substances causing adverse effects in therapeutic use

Primary outcomes

1

Description
blood pressure
Timepoint
before starting. after injection and before tracheal int. after tracheal int
Method of measurement
mmHg by noninvasive automatic device

2

Description
propofol injection pain
Timepoint
during injection
Method of measurement
4 point visual

Secondary outcomes

1

Description
heart rate
Timepoint
before starting. after injection and before tracheal int. after tracheal int
Method of measurement
bit/min by EKG and pulsoximetry

Intervention groups

1

Description
efedrine- 0.1mg/kg- 2cc- iv-before propofol injection
Category
Prevention

2

Description
lidocaine 2%- 2cc- iv- before propofol injection
Category
Prevention

3

Description

ketamine- 0.1mg/kg- 2cc- iv- before propofol injection

Category

Prevention

4

Description

normal saline- placebo- 2cc- iv- before propofol injection

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr Vida Ayatollahi, Anesthesiologist, Assistant professor

Street address

Ebnesina Str, Shahid Ghandi Aven, Shahid Sadughi Hospital

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, ... University of shahid sadoughi medical university

Full name of responsible person

Dr Hassan Mozaffari

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Medical University, Bahonar Square

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Yazd

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, ... University of shahid sadoughi medical university

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi Medical University

Full name of responsible person

Dr Vida Ayatollahi

Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

Anesthesiologist, Member of group, Assistant professor

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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