

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

comparison of effects of ephedrine, lidocaine and ketamine with placebo on injection pain and hypotension & 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 lidocaine 2% (group L, n=35) or ketamine 0.1mg/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

Name

Vida Ayatollahi

Name of organization / entity

Shahid Sadoughi University

Country

Iran (Islamic Republic of)

Phone

+98 35 1821 5730

Email address

ayatt.vida@ssu.ac.ir

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 hypotension & bradycardia due to propofol injection in patient under general anesthesia

Public title

Which drug is better for reducing injection pain and hypotension & 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 as bronchospasms ,) 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 pulseoximetry

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 Sadoughi 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

Street address

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

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University

Full name of responsible person

Dr Vida Ayatollahi

Position

Anesthesiologist, Member of group, Assistant professor

Other areas of specialty/work

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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