Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Clinical trail comparison of effect of Intravenous administration of Lidocaine with the combination of Sufentanyl and Lidocaine on reduction of Propofol induced pain during intravenous injection on patients candidate for General Surgeries

Protocol summary

Summary

Objectives: This study evaluates the effect of Lidocain and the combination of Lidocain and Sufentanyl on the reduction of pain during intravenous injection of Propofol. Design of study: Randomized, Double blind, Control with Placebo, Uni-central, Two trials. Setting and Conduct: After entering the patients into the operating room for the General Surgeries, intravenous way is taken from the vein behind the non-dominant hand with 20 angiocatheter. Premedications like Midazolam, Fentanyl ,etc is not be used for any patients. Tourniquet for catheter insertion is closed on hand and 5cc 0.9 % Normal Saline was injected to one of the groups. The 40 mg Lidocain plus 5 µgr Sufentanyl at dose of 5cc was injected to one of other groups. The 40 mg Lidocain(2 cc) at dose of 5cc was injected to the last group. We will wait one minute then we will open the tourniquet and inject 25% of induction dose of Propofol which is about 0.5 mg per kg of body weight in room temperature to patient, then we will ask the patient about pain existence and severity and then results of patient's response and our observations are recorded according to pain scores and patients skin reactions like, urticaria, redness, etc which is related to injection, are recorded till the end of recovery time. Participants: Patients of 16 to 65 years admitted for General Surgery. Exclusive criteria: The patients who received sedative drugs 24 hours before operation; Have drug allergy; Patients with Neurological Disorders or Mental Disorders; Drug Addicts; Pregnant women; Who requires a rapid induction of anesthesia. Sample size: Three groups of Fifty. Intervention time: One minute after tourniquet closure. Interventions: Lidocaine administered intravenously in a group and Normal Saline in the control group and the combination of Lidocaine and Sufentanyl in the third group before administration of Propofol intravenously with it in the patients who has to be unconscious. Main outcome measures: Pain as continuous independent variable and Drug kinds as nominal independent variable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040515281N7**
Registration date: **2016-05-11, 1395/02/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-11, 1395/02/22

Registrant information

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Seyedebrahim Sadeghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shiraz University of Medical Sience (International Branch)

Expected recruitment start date

2015-05-28, 1394/03/07

Expected recruitment end date
2015-10-29, 1394/08/07
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trail comparison of effect of Intravenous administration of Lidocaine with the combination of Sufentanyl and Lidocaine on reduction of Propofol induced pain during intravenous injection on patients candidate for General Surgeries

Public title
Effect of intervenous administration of Lidocain and Sufentanyl on reduction of Propofol induced pain during intravenous injection
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Patients of 16 to 65 y/o admitted for General Surgery. Exclusion criteria: The patients who received sedative drugs 24 hours before operation; Have drug allergy; Patients with Neurological Disorders or Mental disorders; Drug Addicts; Pregnant women; Who requires a rapid induction of anesthesia.
Age
From **16 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **150**
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 Shiraz University of Medical Sience (International Branch)
Street address
Shiraz University of Medical Sinces(Internatinal branch), Accidents and Burn Hospial, Sadra Road 3th Km
City
Shiraz
Postal code
Approval date
2016-03-06, 1394/12/16
Ethics committee reference number
IR.sums.rec.1394.222

Health conditions studied

1

Description of health condition studied
Complications of anaesthesia
ICD-10 code
T88.5
ICD-10 code description
other complication of anesthesia

Primary outcomes

1

Description
The pain measurment of Intravenous ejction of Propofol If perviously Useage interavenous ejection of Lidocaine
Timepoint
1 minute after injection of Lidocaine, propofol injected and evalute The pain
Method of measurement
Fill questionare and visual scale

2

Description
The measurment of Intravenous ejection of Propofol If perviously Useage of Intravenous Combination of Lidocaine +Sufentanyl
Timepoint
1 minute after injection of Combination of Lidocaine +Sufentanyl ,Propofol injeceted and evalute The pain
Method of measurement
Fill questionare and visual scale

Secondary outcomes

1

Description
Dermal side effects
Timepoint
From injection time untii ending of recovery time
Method of measurement
Fill questionare

Intervention groups

1

Description
Interventional group: thirth group,5 micro gram sufantany + 40 mg lidocainl, 5 cc , 1 min before propofol injection
Category
Treatment - Drugs

2

Description
Control group: first group, 5 cc normal salin 0.9 , 1 min before propofol injection
Category
Treatment - Drugs

3

Description
Interventional group: second group, 40 mg lidocain, 5 cc , 1 min before propofol injection
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Marvdasht Motahari hospital
Full name of responsible person
DR Seyed Ebrahim Sadeghi
Street address
Marvdasht Motahari hospital, Moallm squere, Marvdasht Far
City
Marvdasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of International Branch,Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ali Akbari
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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
Vice chancellor for research of International Branch,Shiraz University of Medical Sciences
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
Name of organization / entity
Mrvdasht Motahari hospital
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DR Seyedebrahim Sadeghi
Position
Anesthesiologist, Assistant Professor of intensive care unit of Shiraz University of Medical Sinces
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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