

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Clinical trial 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 Lidocaine and the combination of Lidocaine 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 Lidocaine plus 5 µgr Sufentanyl at dose of 5cc was injected to one of other groups. The 40 mg Lidocaine(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

Name

Seyedebrahim Sadeghi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 4333 3278

Email address

esadeghi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shiraz University of Medical Science (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 trial 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.

AgeFrom **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

Science (International Branch)

Street address

Shiraz University of Medical Sciences(International branch), Accidents and Burn Hospital, 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 measurement of Intravenous ejection 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 questionnaire and visual scale

2**Description**

The measurement 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 injected and evalute The pain

Method of measurement

Fill questionnaire and visual scale

Secondary outcomes**1****Description**

Dermal side effects

Timepoint

From injection time untill ending of recovery time

Method of measurement

Fill questionnaire

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 square,
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

Street address

Shiraz University Medical Sinences (Interntinoal
branch),Accidents and Burns Hospial ,Sadra Road 3th
Km

City

Shiraz

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

Full name of responsible person

DR Seyedebrahim Sadeghi

Position

Anesthesiologist, Assistant Professor of intensive care
unit of Shiraz University of Medical Sinces

Other areas of specialty/work

Street address

Marvdasht Motahari hospital, Moallm square,
Marvdasht Fars

City

Marvdasht

Postal code

Phone

+98 71 4334 2060

Fax

Email

seydebrahims@yahoo. com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Marvdasht Motahari hospital

Full name of responsible person

Dr Seyed Ebrahim Sadeghi

Position

Anesthesiologist, Assistant Professor of intensive care
unit of Shiraz University of Medical Sinces

Other areas of specialty/work

Street address

Marvdasht Motahari hospital, Moallm square,
Marvdasht, Fars

City

Marvdasht

Postal code

Phone

+98 71 4333 3278

Fax

Email

esadeghi@sums.ac.ir

Web page address

+98 71 4471 6699

Fax

Email

esadeghi@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Marvdasht Motahari hospital

Full name of responsible person

Dr Seyedebrahim Sadeghi

Position

Anesthesiologist, Assistant Professor of intensive care
unit of Shiraz University of Medical Sciences

Other areas of specialty/work

Street address

Marvdasht Motahari hospital, Moallm square,
Marvdasht, Fars

City

Marvdasht

Postal code

7144716699

Phone

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