

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Clinical trial comparison of effect of Intravenous administration of Lidocaine with the combination of Mepridine and Lidocaine on reduction of Propofol induced pain on patients candidate for General Surgeries.

Protocol summary

Summary

Objectives: This study evaluates the effect of Lidocaine and the combination of Lidocaine and Mepridine on reduction of Propofol induced pain during intravenous injection of Propofol. **Design of study:** The study was done as a randomized clinical trial; control with placebo, uni-central, Two trails. **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. **Torniquet** for catheter insertion is closed on hand and 5cc 0.09% saline was injected to one of the groups. the 40 mg Lidocaine plus 25 mg Mepridine at dose of 5cc was injected to one of the other groups. The 40 mg lidocaine (2cc) at dose of 5cc was injected to the last group. we will wait one minute then we will open the torniquet and inject 25% of induction dose of Propofol Which is about 0.0mg/kg of bodyweight in room temprature to patient, Then we will ask the patient about pain existance and severity and then results of patients response and our observations are recorde according to pain scores and patients skin reactions like, urticaria, redness, etc Which us related to injection, our recoded till the end of recovery time. **Participants:** Patients of 16-65 years addmitted for General Surgery . **Exclusive criteria:** The patients who recived sedative drugs 24 h before operation; Have drug allergy; Patients with Neurological Disorders or Mental Disorders: **Drugs Addicts:** Pregnant Women: Who requires a rapid induction of anesthesia. **Sample size:** Three groups of 50. **Interventions time:** One minute after tourniquet closure. **Interventions:** Lidocain adminstered intravenously in a group and Normal Salin in the control group and the combination of Lidocain and Mepridine in the third group before administration of Profol intravenously with it in the patient who has to be unconscious. **Main outcome**

messures: Pain as contineouse independent variable and Drug kinds as nominal independet variable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042315281N8**

Registration date: **2016-06-10, 1395/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-10, 1395/03/21

Registrant information

Name

Seyedebrahim Sadeghi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shiraz Univesity of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-02-20, 1394/12/01

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 Mepridine and Lidocaine on reduction of Propofol induced pain on patients candidate for General Surgeries.

Public title
The effect of intravenous administration of lidocaine and lidocaine + mepridine 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: Patients who received sedative drugs 24h before operation; Have drug allergy; With Neurological or Mental disorders; Drug Addicts; Pregnant Women; Who require of rapid induction of anesthesia and Who received long term steroid therapy.

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 Sciences(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
2016-05-29, 1395/03/09

Ethics committee reference number
IR.SUMS.REC.1395.37

Health conditions studied

1

Description of health condition studied
Complications of anesthesia

ICD-10 code
T88.5

ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
The pain measurement of intravenous injection of Propofol if previously usage intravenous injected Lidocaine

Timepoint
1 minute after injection of Lidocaine,Propofol injected and evaluate the pain

Method of measurement
Fill questionnaire and visual scale

2

Description
The measurement of intravenous injection of intravenous combination of Lidocaine and Mepridine

Timepoint
1 minute after injection of lidocaine and mepridine,Propofol injected and evaluate pain

Method of measurement
Fill questionnaire and visual scale

Secondary outcomes

1

Description
Dermal side effects

Timepoint
From injection time until ending of recovery time

Method of measurement
Fill questionnaire

Intervention groups

1

Description

Control group:First group,5 cc normal saline 0.9 , 1 minute before propofol injection

Category

Treatment - Drugs

2

Description

Interventional group:Second group,40 mg Lidocaine +25 mg Mepridine (5cc),1 minute before propofol injection

Category

Treatment - Drugs

3

Description

Interventional group:Third group,40 mg Lidocaine (5cc),1 minute before propofol injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran

Full name of responsible person

Seyed Ebrahim Sadeghi

Street address

Marvdasht Motahari Hospital,Mpallem square,Marvdasht,Fars

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 Hamidreza Bahmani

Street address

Marvdasht Motahari hospital,Moallem square,

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

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 Sciences

Other areas of specialty/work

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Marvdasht Motahari Hospital

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Position

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Fax**Email****Web page address****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