

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of effect of intravenous administration of Lidocaine-Fentanyl and lidocaine on reduction of propofol induced pain during intravenous injection

Protocol summary

Summary

In this study, it is attempted to evaluate the effect of two drugs ,Lidocaine and Fentanyl, as combination, comparing to Lidocaine alone on reduction of Propofol venous injection induced pain. This study is a double-blinded clinical trial that was conducted on 150 patients who were waiting for the general anaesthesia. The patients were divided into three separated groups. Inclusion criteria: 16-74 years of age, no history of any cardiovascular disease , autoimmune disease and diabetes. Exclusion Criteria: receiving of analgesics and sedative drugs 24 hours prior to surgery, any drug allergy, neurologic and/or psychologic disease, drug addicts, pregnant women, patients requiring rapid induction of anaesthesia. In each of the three groups, the venous blood flow of the desired hand was blocked via a tourniquet at elbow site. In the first group, 5cc of normal saline 0.9% , in the second group 40mg of Lidocaine +50 µg Fentanyl (diluted to 5cc) and in the third group , 40 mg Lidocaine (diluted to 5cc) were injected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051215281N9**

Registration date: **2017-01-11, 1395/10/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-11, 1395/10/22

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 Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of intravenous administration of Lidocaine-Fentanyl and lidocaine on reduction of propofol induced pain during intravenous injection

Public title

Comparison of effect of intravenous administration of Lidocaine-Fentanyl and lidocaine on reduction of propofol induced pain during intravenous injection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients should be 16-74 years of age, they shouldn't have any cardiovascular, autoimmune

disease and diabetes. Exclusion Criteria: patients who received sedative drugs 24 hours prior to surgery, any drug allergy, neurologic and/or psychologic disease, drug addicts, pregnant women, patients requiring rapid induction of anesthesia.

Age

From **15 years** old to **74 years** old

Gender

Both

Phase

N/A

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

randomised via following website: www.random.org

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand st., Shiraz Medical University of Shiraz

City

Shiraz

Postal code

Approval date

2015-05-17, 1394/02/27

Ethics committee reference number

IR.SUMS.REC.1394.29

Health conditions studied

1

Description of health condition studied

Complication of anaesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes

1

Description

effect of lidocaine on reduction of propofol induced pain

Timepoint

1 minute after injection of propofol

Method of measurement

questionnaire and defined pain scale

2

Description

Effect of Lidocaine+Fentanyl on reduction of propofol induced pain

Timepoint

1 minute after injection of propofol

Method of measurement

Questionnaire and defined pain scale

Secondary outcomes

empty

Intervention groups

1

Description

control group: 5cc of normal saline 0.9%, one minute before induction dose of propofol was injected. Propofol lipuro braun Germany

Category

Treatment - Drugs

2

Description

Interventional group: second group 40mg of Lidocaine +50 µg Fentanyl (diluted to 5cc), one minute before injection of induction dose of propofol. Lidocaine Iran hormone- Iran Fentanyl Aburaihan-Iran

Category

Treatment - Drugs

3

Description

Interventional group: Third group 40 mg Lidocaine (diluted to 5cc), one minute before injection of induction dose of propofol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari hospital of Marvdasht, Iran

Full name of responsible person

Seyed Ebrahim Sadeghi

Street address**City**

Marvdasht

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Ebrahim Sadeghi

Position

Anesthesiologist- Assistant Professor

Other areas of specialty/work**Street address**

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Postal code**Phone**

+98 71 4333 3278

Fax**Email**

esadeghi@sums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for International branch of Shiraz Medical Sciences

Full name of responsible person

Dr. Kazem Samadi

Street address

Sadra, International branch of Shiraz Medical Sciences

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 International branch of Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Ebrahim Sadeghi

Position

Anesthesiologist-Assistant Professor

Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****Name of organization / entity**

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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