Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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
Shahid Motahari Hospital of Marvdasht
City
Marvdasht
Postal code
Phone
+98 71 4333 3278
Fax
Email
esadeghi@sums.ac.ir
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
Shahid Motahari Hospital of Marvdasht
City
Marvdasht
Postal code
Phone
+98 71 4333 3278
Fax
Email
esadeghi@sums.ac.ir
Web page address

Person responsible for updating data

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
Motahari Hospital of Marvdasht
City
Marvdasht
Postal code
Phone
+98 71 4333 3278
Fax
Email
esadeghi@sums.ac.ir
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