

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effects of bilateral intrapleural infusion of Lidocaine and Fentanyl versus Lidocaine for pain relief in Coronary Artery Bypass surgery patients

Protocol summary

Summary

The goal of study is to evaluation the effects of bilateral intrapleural infusion of lidocaine and Fentanyl versus lidocaine for pain relief in CABG surgery. Inclusion criteria: EF $\geq$ 30%; cratinine $\leq$ 1.8; elective CABG; age 20 -60 years. exclusion criteria: EF< 30 %; cratinine>1.8; sensitivity to local anesthetics; addiction to opiums; bleeding more than 1000 ml/24h. After approval from university ethical committee and obtaining written consent from patients, the prospective randomized, double-blind clinical trial will be done on 130 patients 20 to 60 years undergoing coronary artery bypass surgery between 3 to 6 hours in the Tabriz Shahid Madani hospital. At the end of the operation two-sided suction catheter will be placed into the pleural space. Patients will be divided in lidocaine and fentanyl group (group A) (65 patients) and lidocaine group (group B) (65 people) and at the end of surgery and ICU every 6 hours, 20 ml of lidocaine 0.75% + fentanyl 2mcg / kg in group A and 20 mL of lidocaine 0.75% in group B will be injected through the intraplural catheter. The pain in all patients will evaluate using (Visual analog scale VAS) every 2 hours . VAS and the type and total amount of analgesic drug consumption will be recorded. P value <0.05 was considered significant

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015112714728N2**

Registration date: **2015-12-12, 1394/09/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name

Kamran Shadvar

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 1994

Email address

shadvark@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2016-01-30, 1394/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of bilateral intrapleural infusion of Lidocaine and Fentanyl versus Lidocaine for pain relief in Coronary Artery Bypass surgery patients

Public title

Evaluation the effects of bilateral intrapleural infusion of Lidocaine and Fentanyl versus Lidocaine for pain relief in Coronary Artery Bypass surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: EF $\geq$ 30%; cratinine $\leq$ 1.8; elective CABG; age 20 -60 years exclusion criteria: EF< 30 %; cratinine>1.8; history of plural disease; COPD; sensitivity to local anesthetics; addiction to opiums; drug habits to analgesics, calcium channel blockers, α 2 agoniste; history of cardiac surgery and as a surgery complications such as aortic dissection, reoperation due to bleeding; bleeding more than 1000 ml/24h

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 130

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

Street address

Central building of Tabriz University of Medical Sciences, Daneshgah street

City

Tabriz

Postal code**Approval date**

2015-02-09, 1393/11/20

Ethics committee reference number

93172

Health conditions studied**1****Description of health condition studied**

Pain

ICD-10 code

R07.4

ICD-10 code description

Chest pain, unspecified

Primary outcomes**1****Description**

Pain

Timepoint

every 2 hours

Method of measurement

VAS

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

Duration of ICU stay

Timepoint

After Intervention

Method of measurement

Hour

Intervention groups**1****Description**

In intervention group: 20 ml of lidocaine 0.75% + fentanyl 2mcg/kg solution will be administered via intraplural catheter every 6 hours up to 24 hours.

Category

Treatment - Drugs

2**Description**

In control group: 20 ml of lidocaine 0.75% solution will be administered via intraplural catheter every 6 hours up to 24 hours.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Madani Hospital

Full name of responsible person

Dr. Kamran Shadvar

Street address

Daneshgah st, Shahid Madani Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Magami

Street address

Central building of Tabriz University of Medical Sciences, Daneshgah street

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Kamran Shadvar

Position

ICU Fellowship

Other areas of specialty/work

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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