Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparision of effectiveness of lidocaine intravenous infusion with morphine intravenous infusion on acute ischemic pain in patients suspicious of having critical limb ischemia in shariatti hospital. (2012-2013)

Protocol summary

Summary

The aim of this study is to compare the efficacy of intravenous lidocaine versus intravenous morphine for pain management in acute critical limb ischemia. Patients with symptoms of limb ischemia (Pain-paralysis - pulselessness-paresthesia-pallor) and no contraindications to lidocaine and morphine are entered into the study.All patient population over age 15 are admitted in the emergency ward of Shariati Hospital.The study sample size is a total of 40 patients20 patients in each group.This study is a double blind randomized control trial. For patients randomly assigned, a random binary codes are pre-designed and planed by the physician in charge. Written informed consent of all patients participating in the study will be taken. Intervention in the control group is intravenous lidocaine with a dose of 2mg/kg and in the case group intravenous morphine with a dose of 0.1 mg/kg. The primary outcome variable is the pain, according to Visual Analogue Scale pain scoring system which is taken from the patients at the beginning of the intervention and 15 and 30 minutes later. HR, BP, Pulse oximetry are also checked at 0,15, 30 minutes. ECG of all patients should be recorded because of the incidence of cardiac arrhythmias. After 40% of the sample size is collected and if serious unwanted side effects of lidocaine has occurred we will stop the rest of it.(interim analysis) If each on of the two drugs are not effective in reducing pain after 30 minutes, we will substitute IV Fentanyl instead.(Revers analgesia)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210148872N2**

Registration date: **2012-11-18, 1391/08/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-18, 1391/08/28

Registrant information

Name

Morteza Saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2719

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m_saeedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences- Faculty of MedicineVice Chancellor for Research

Expected recruitment start date

2012-10-01, 1391/07/10

Expected recruitment end date

2013-12-31, 1392/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of effectiveness of lidocaine intravenous infusion with morphine intravenous infusion on acute

ischemic pain in patients suspicious of having critical limb ischemia in shariatti hospital. (2012- 2013)

Public title
The effectiveness of intravenous Lidocaine versus Morphine in pain management in acute critical limb ischemia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: having clinical signs and symptoms of acute critical limb ischemia which are known with 5P (Pain-paralysis – pulselessness- paresthesia- pallor) and is diagnosed by an emergency medicine specialist. Consent to join in the study is required and the form is read and signed by each one of the patients. Exclusion criteria: contraindications of lidocaine and morphine: lung problems (including acute asthma; pulmonary edema); Heart conditions(including heart failure; cardiogenic shock; Block degree three; arrhythmia WPW and Stoke Adams syndrome); neurological problems(including seizures; changes in state of consciousness); chronic pain in another site; pregnancy; use of pain killers in recent week; allergy to lidocaine or morphine; addiction; prescription of opioid drugs intravenously by EMS or triage nurses; respiratory distress; blood pressure <100mmhg; trauma; altered level of consciousness; language problems and dementia.

Age
From **15 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Ethics review committee of Tehran University of Medical Siences-Faculty of Medicine,Dr Akbar fotouhi

Street address
floor 5, NO 226,Poursina avenue, Ghods avenue,Enghelab square, Tehran

City
Tehran

Postal code
1417653761

Approval date
2012-09-16, 1391/06/26

Ethics committee reference number
130/1290/91/د

Health conditions studied

1

Description of health condition studied
acute pain in critical limb ischemia

ICD-10 code
I74

ICD-10 code description
Arterial embolism and thrombosis

Primary outcomes

1

Description
Pain scoring

Timepoint
0-15-30 Min after the begining of study

Method of measurement
visual analogue scale

Secondary outcomes

1

Description
side effect

Timepoint
0-15-30 min after the begining of study

Method of measurement
by name

2

Description
Blood pressure

Timepoint
0-15-30 min after the begining of study

Method of measurement
mm/hg

3

Description
Heart rate

Timepoint
0-15-30 min after the begining of study

Method of measurement

beats per min

4

Description
Pulse oximetry
Timepoint
0-15-30 min after the begining of study
Method of measurement
%

Intervention groups

1

Description
Intravenous infusion of Lidocaine 2mg/kg at the rate of 5cc/min with close cardiac monitoring in the control group
Category
Treatment - Drugs

2

Description
Intravenous infusion of Morphine 0.1 mg/kg at the rate of 5cc/min with close cardiac monitoring in the case group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency Department of Imam Khomeini and Shariati Hospitals
Full name of responsible person
Dr Morteza Saeedi
Street address
Imam Khomeini hospital (at the end of Keshavarz Boulvar; Enghelab square)and Shariati Hospital(beside Eghtesad university; Al Ahmad high way; North Kargar avenue) Emergency Departement
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences -Faculty of Medicine
Full name of responsible person
Dr Shahin Akhundzade
Street address
Vice Chancellor for Research of Tehran ,University of Medical Sciences, Poursina Avenue, Enghelab Square
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences -Faculty of Medicine
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
Tehran University of Medical Sciences-Faculty of Medicine emergency departement
Full name of responsible person
Dr Elnaz vahidi
Position
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
ED of Shariati and Imem Khomeini hospitals
Full name of responsible person
Dr elnaz vahidi
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Other areas of specialty/work
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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