

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 patients 20 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

Email address

m_saeedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences- Faculty of Medicine
Vice 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

130/1290/91/3

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 beginning 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

emergency medicine resident

Other areas of specialty/work

Street address

No1, Floor 4 Golsorkh alley, Golzar avenue, Nobonyad square

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evahidi62@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shariati Emergency Department staff

Full name of responsible person

Dr Morteza saeedi

Position

emergency medicine assistant professor

Other areas of specialty/work

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Shariati hospital ED (beside Eghtesad university; Al Ahmad high way; North Kargar avenue)

City

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Phone

+98 21 8490 2719

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Web page address**Phone**

+98 21 2293 9197

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Web page address**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

Position

emergency medicine resident

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

No1, Floor 4 Golsorkh alley, Golzar avenue, Nobonyad square

City

Tehran

Postal code**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