Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of intravenous non-vented lidocaine effects in the relief of acute pain in extremity trauma patients

Protocol summary

Study aim
Comparison of intravenous morphine and nebulized lidocaine in acute pain relief in limb trauma patients.

Design
In this study, 100 patients referred to the emergency department with severe acute traumatic trauma were examined. A single dose of nebulized lidocaine, 10 mg / kg, was administered to the intervention group. A single dose of intravenous morphine 0.1 mg / kg was administered to the control group. Patients are randomly divided into two groups by a statistician using statistical software.

Settings and conduct
In this study, 100 patients who referred to the emergency department with acute traumatic trauma were evaluated after obtaining consent, provided that they did not have any restrictions on the participation in the project. Patients were randomly assigned a 10 mg / kg lidocaine nebulizer or morphine Intravenous administration of 0.1mg / kg is prescribed and the severity of pain and vital signs of the patient is specified in minutes 0.10, 20.30, 60. Finally, we analyze the data.

Participants/Inclusion and exclusion criteria
Inclusion criteria : 1- Age over 16 years and under 65 years 2. Traumatic traumatic limbs require pain relief due to extreme pain in the limbs 3. Pain intensity greater than 5 based on NRS scale 4. Satisfaction to enter the study Exclusion criteria: 1. Disturbance of alertness 2. Hemodynamic impairment during injection of the drug 3. Drug or alcohol use, or pain relief or analgesics over the past 48 hours. 4. Lidocaine and morphine susceptibility 5. Chronic illnesses (heart disease, liver, biliary tract, kidney and lung) according to history and clinical examination. 6. No patient cooperation 7. No consent to enter the study

Intervention groups
Intervention group:Prescribing nebulized lidocaine in patients with acute limb trauma. Control group:Prescribing intravenous morphine in patients with acute limb trauma.

Main outcome variables
The amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180131038569N1**
Registration date: **2018-04-12, 1397/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-12, 1397/01/23**
Update count: **0**

Registration date
2018-04-12, 1397/01/23

Registrant information

Name
Behzad Sadeghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6690 4848

Email address
b.s1367@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-08-23, 1396/06/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous non-vented lidocaine effects in the relief of acute pain in extremity trauma patients

Public title

Comparison of intravenous non-vented lidocaine effects in the relief of acute pain in extremity trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with limb trauma require pain relief with NRS upper 5/10 age between16-65 years

Exclusion criteria:

dissatisfaction of patient from this study Patient's allergy to lidocaine or morphine

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized, double blind clinical trial. All patients with entry criteria at the time of study are considered to be included in this study. After obtaining written consent and explaining the study conditions, patients are asked to rate their pain levels based on the NRS score. They then randomly enter each of the groups under review. The first group was treated with intravenous morphine (0.1 mg / kg, manufactured by Dr. Distribution Co., Tehran, Iran) and the second group with nevulose lidocaine (10mg / kg in saline (100 mg / ml concentration), Caspian Company Medicine, Rasht, Iran) were treated.

Blinding (investigator's opinion)

Double blinded

Blinding description

The grouping of patients will be based on Balanced Block Randomization in two groups A and B. Both the analgesic drugs are in boxes A and B, and only the physician responsible for the plan (supervisor) is aware of the drug content of each group. In the control group intravenous morphine is selected and at the same time is nebulized distilled water as placebo and in the intervention group,nebulized lidocaine, and at the same time, venous injection distilled water for patients will be prescribed. Then, for use by each supervisor, the numbering is done by the supervisor and what is mentioned in the office.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital,Keshavarz Blvd,Tehran

City

Tehran

Province

Tehran

Postal code

1417614418

Approval date

2017-06-12, 1396/03/22

Ethics committee reference number

IR.TUMS.IKHC.REC1396.2600

Health conditions studied

1

Description of health condition studied

درد حاد در اورژانس

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Intensity of pain

Timepoint

0,10,20,30,60 minutes

Method of measurement

Numeric Pain Rating Scale

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

0,10,20,30,60minutes

Method of measurement

MmHg

2

Description
Diastolic blood pressure
Timepoint
0,10,20,30,60minutes
Method of measurement
MmHg

3

Description
Heart rate
Timepoint
0,10,20,30,60minutes
Method of measurement
In a minute

4

Description
Respiratory rate
Timepoint
0,10,20,30,60minutes
Method of measurement
In a minute

5

Description
o2 saturation
Timepoint
0,10,20,30,60minutes
Method of measurement
percent

Intervention groups

1

Description
Intervention group: Lidocaine nebulizer is administered at a dose of 10 mg / kg and is administered intravenously to placebo (distilled water 0.1 cc / kg) for patients.
Category
Treatment - Drugs

2

Description
Control group: Intravenous morphine (0.1 mg / kg) with distilled water as a placebo (10 cc / kg) is nebulized.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital complex
Full name of responsible person
Behzad Sadeghi Amroabadi
Street address
Imam Khomeini Hospital Complex,End of Keshavarz Boulevard,Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2240
Fax
+98 21 6658 1615
Email
Imamhospital@tums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research of Tehran University of Medical Sciences
Full name of responsible person
Dr Shervin Farahmand
Street address
Imam Khomeini Hospital,Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1618
Email
Imamhospital@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research of Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Deputy of Research of Tehran University of Medical Sciences
Full name of responsible person
Behzad Sadeghi Amroabadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Imam Khomeini Hospital,Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417614418
Phone
+98 21 61111
Email
B.s1367@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Deputy of Research of Tehran University of Medical Sciences
Full name of responsible person
Dr Shervin Farahmand
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Imam Khomeini Hospital,Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
Imamhospital@tums.ac
Phone
+98 21 6658 1618
Email
Shervinf1352@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Deputy of Research of Tehran University of Medical Sciences
Full name of responsible person
Behzad Sadeghi Amroabadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Keshavarz Avenue,Enghelab Square
City
Tehran
Province
Tehran
Postal code
Imamhospital@tums.ac
Phone
+98 21 6658 1618
Email
B.s1367@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available