

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of intravenous lidocaine in comparison with intravenous morphine in patients referred to Imam Khomeini hospital with right upper abdominal pain and suspected billiary colic during 2016-18

Protocol summary

Study aim

Pain relief, expedite digestive function, reducing the duration of hospitalization

Design

randomized blinded clinical trial with a parallel group design recruiting 100 patients

Settings and conduct

After receiving consent, drugs will deliver to the Head nurse based on 0 and 1 sequence. Drugs include intravenous morphine 5 miligram and intravenous lidocaine 100 miligram that inject to patient with the same shape and volume, then we study vital signs and severity of the pain.

Participants/Inclusion and exclusion criteria

based on location and severity of pain and past medical history

Intervention groups

The group that have biliary colic and treat with intravenous lidocaine

Main outcome variables

severity of pain and drug complications, blood pressure, respiratory rate, pulse rate, oxygen saturation and resque dose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161121030993N2**

Registration date: **2018-02-23, 1396/12/04**

Registration timing: **retrospective**

Last update: **2018-02-23, 1396/12/04**

Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

Tayebeh Pouryousefi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2240

Email address

t-pouryousefi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-01-07, 1395/10/18

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2017-01-07, 1395/10/18

Actual recruitment end date

2018-01-08, 1396/10/18

Trial completion date

empty

Scientific title

Evaluation of intravenous lidocaine in comparison with intravenous morphine in patients referred to Imam Khomeini hospital with right upper abdominal pain and suspected billiary colic during 2016-18

Public title

Comparison of Lidocaine Effect with Venous Morphine in Patients with Billiary Colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
upper abdominal pain score more than 5/10 past biliary history positive morphy sign positive sonography

Exclusion criteria:
renal failure hepatic failure heart block wolf-parkinson-white syndrome betablocker user or cimethidine user weight under 40 kilogram weight over 90 kilogram

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment by Statistician with software

Blinding (investigator's opinion)
Double blinded

Blinding description
Medications in the 5cc syringes are treated with morphine valodicin in accordance with the sequences 0 and 1, which are delivered to the head nurse. Patients and researcher are blind.

Placebo
Not 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

16Azar Avenue, Enghelab Square, Tehran

City

Tehran

Province

Tehran

Postal code

1417614418

Approval date

2017-01-07, 1395/10/18

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.1425

Health conditions studied

1

Description of health condition studied

Billiary stone

ICD-10 code

K80

ICD-10 code description

Cholelithiasis

Primary outcomes

1

Description

Intensity of pain

Timepoint

At minutes: 0, 10, 20, 30, 45, 60 and 120

Method of measurement

Numeric Rating Scale Score

Secondary outcomes

1

Description

Blood Pressure

Timepoint

0, 20, 60 minutes after

Method of measurement

Barometer device

2

Description

pulse rate

Timepoint

0, 10, 20, 30, 45, 60, 120 minutes after

Method of measurement

minute

3

Description

Respiratory rate

Timepoint

0, 20, 60 minutes after

Method of measurement

minute

4

Description

Oxygen saturation

Timepoint

0, 20, 60 minutes after

Method of measurement

pulse oxymeter device

5

Description

Numeric Rating Scale Score

Timepoint

0, 10, 20, 30, 45, 60, 120 minutes after

Method of measurement

Numeric range from 0 to 10

Intervention groups

1

Description

Patients with acute Biliary Colic with NRS above 5/10 that taking 100 miligram Intravenous Lidocaine

Category

Treatment - Drugs

2

Description

Control group: Patients with acute Biliary Colic with NRS above 5/10 that taking 5 miligram Intravenous Morphine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

طیبه پوریوسفی کوذهی

Street address

Imam khomeini hospital, Keshavarz avenue, Enghelab square

City

Tehran

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Tehran

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1419733141

Phone

+98 21 6658 1618

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Hooman Hoseinnejad

Street address

Imam Khomeini hospital, Keshavarz Blvd.

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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

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

Tehran University of Medical Sciences

Full name of responsible person

Tayebe Pouryousefi koodehi

Position

Emergency Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Hooman Hoseinnejad

Position

Professor,associate

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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dr.tayebe.pouryousefi@gmail.com

Web page address**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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Tayebe.Pouryousefi koodehi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address