Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of lidocaine infusion during laparotomy surgery on the reduction of postoperative pain and the amount of opioid consumption to control postoperative pain.

Protocol summary

Study aim
The effect of lidocaine infusion during laparotomy surgery on the reduction of postoperative pain and the amount of opioid consumption to control postoperative pain.

Design
A controlled, parallel-group, phase 3, randomized, double-blind clinical trial on 60 patients. A table of random numbers was used for randomization.

Settings and conduct
The current study is a clinical trial on patients undergoing laparotomy surgery referred to the hospitals of Shahid Beheshti University of Medical Sciences. In the intervention group, 1% lidocaine was administered with a bolus dose of 1mg/kg as a slow intravenous injection, and then its infusion continued with a dose of 1mg/kg/h until the end of the operation. In the control group, normal saline infusion is used instead of lidocaine.

Participants/Inclusion and exclusion criteria
Inclusion criteria include no sensitivity to local anesthetics, no chronic use of narcotics and painkillers, no use of steroids, age between 18 and 85 years, no pregnancy, ASA Class one and two patients. Body mass index less than 40 kg/m2, heart rate more than 50 beats per minute, recovery time less than 45 minutes, interval between P wave and R wave in ECG not more than 0.2 seconds. Exclusion criteria include severe drop in blood pressure, severe bradycardia, moderate reduction in arterial pressure, arrhythmia or Urticaria, or patients whose surgery lasts more than 4 hours.

Intervention groups
In the intervention group, after induction of anesthesia, administration of 1% lidocaine with a bolus dose of 1mg/kg as a slow intravenous injection It is done and then its infusion continues with a dose of 1mg/kg/h until the end of the operation. In the control group, normal saline infusion is used instead of lidocaine.

Main outcome variables
The intensity of the pain; the amount of systemic painkillers; Length of hospitalization

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240619062178N1**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**
Update count: **0**

Registration date
2024-06-22, 1403/04/02

Registrant information
Name
Seyed hossein Ardehali
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 25719
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-07-22, 1403/05/01
Expected recruitment end date
2024-10-22, 1403/08/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of lidocaine infusion during laparotomy surgery on the reduction of postoperative pain and the amount of opioid consumption to control postoperative pain.

Public title
The effect of lidocaine infusion on pain reduction and the amount of opioid consumption after surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing laparotomy surgery with no sensitivity to local anesthetics No chronic use of narcotics and painkillers No use of steroids Age between 18 and 85 years Absence of pregnancy Patients according to American Society of Anesthesiologists (ASA) class one and two Body mass index less than 40 kg/m2 Heart rate above 50 beats per minute The recovery time is less than 45 minutes The interval between the P wave and the R wave in the ECG is no more than 0.2 seconds
Exclusion criteria:
Patients who experience a severe drop in blood pressure, severe bradycardia (heart rate less than 40 beats per minute), moderate arterial pressure drop (mean blood pressure less than 60 mm Hg), arrhythmia, or urticaria during surgery following intravenous administration of lidocaine. Patients whose surgery lasts more than 4 hours.
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, a table of random numbers was used, in order to create a random sequence using a table of random numbers by a statistical consultant, the patients were randomly given one of the even and odd codes, the patients with even codes were placed in the first group and the odd codes were placed in the second group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medicines in envelopes that are similar in appearance are labeled as group A and B. The patient does not know about this labeling, nor does the drug distributor's colleague know about the labeling. In order to avoid any possible complications, the main researcher is aware of the allocation of groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahid Beheshti University of Medical Sciences Vice President of Resear
Street address
Yemen St, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1083969411
Approval date
2023-12-26, 1402/10/05
Ethics committee reference number
IR.SBMU.MSP.REC.1402.493

Health conditions studied

1

Description of health condition studied
Laparotomy surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity of pain
Timepoint
After the surgery in the recovery unit and 24 hours after the operation in the ward
Method of measurement
Using a numerical rating scale

2

Description
The amount of systemic painkillers used in recovery and the ward
Timepoint

After the surgery in the recovery unit and 24 hours after the operation in the ward

Method of measurement

Using a numerical rating scale

3

Description

Length of hospitalization

Timepoint

After the surgery in the recovery unit and 24 hours after the operation in the ward

Method of measurement

Using a numerical rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After induction of anesthesia using midazolam fentanyl as premedication, propofol as hypnotic and etracorium as muscle relaxant, two minutes before intubation until surgical incision, administration of 1% lidocaine with a bolus dose of 1mg/kg is done as a slow intravenous injection. Then its infusion continues with a dose of 1mg/kg/h until the end of the operation.

Category

Treatment - Surgery

2

Description

Control group: In the control group, normal saline infusion is used instead of lidocaine.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahada Tajrish Hospital

Full name of responsible person

Seyed Hossein Ardehali

Street address

Shahrdari St, Quds Square, Tajrish

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Hossein Ardehali

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Critical Care Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed Hossein Ardehali

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Critical Care Medicine

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Person responsible for updating data

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Full name of responsible person
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Researcher

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Ph.D.

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Medical Genetics

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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