

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison the effect of intravenous infusion of lidocaine with of 1 mg / kg / h and 2mg/ kg / h on reducing pain and nausea-vomiting after surgery of Stomach Bypass with Laparoscopy

Protocol summary

Summary

Objectives: To compare the two doses of intravenous lidocaine on pain and nausea-vomiting after surgery of Stomach Bypass with Laparoscopy Design: 40 patients admitted to hospital for Laparoscopy then they divided into two groups. Intravenous lidocaine infusion at doses of 1 mg and 2 mg, according to each group, were taken during surgery. Then pain, nausea-vomiting, both static and dynamic in PACU and surgical ward at zero, half an hour, one and six and twelve and twenty-four hours and agitation rate, systolic and diastolic blood pressure and heart rate in both groups A, B at time zero, half an hour and one hour after the operation compared. Inclusion criteria: patient consent, age greater than 18 and less than 60 years; BMI less than 50; ASA equal to or less than 3; Intraoperative lidocaine infusion time up to 4 hours; no sensitivity to lidocaine; no heart diseases; no liver diseases; no kidney diseases; no psychiatric diseases; Avoiding the use of alcohol and drugs addiction Exclusion criteria: Withdraw from the study; Intraoperative lidocaine infusion time more 4 hours; conversion laparoscopy to laparotomy Interventions include: Intravenous infusion of lidocaine during surgery with values of 1 mg / kg / h and / kg / h 2 mg The main outcome variables were: pain, nausea-vomiting, both static and dynamic in PACU , agitation rate, systolic blood pressure, diastolic blood pressure and heart rate after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121924754N2**

Registration date: **2015-12-26, 1394/10/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-26, 1394/10/05

Registrant information

Name

Neda Hajiha

Name of organization / entity

Tehran University of Medical Sciences

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Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intravenous infusion of lidocaine with of 1 mg / kg / h and 2mg/ kg / h on reducing pain and nausea-vomiting after surgery of Stomach Bypass with Laparoscopy

Public title

The effect of intravenous infusion of lidocaine during surgery on pain and nausea-vomiting in Stomach Bypass with Laparoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient consent, age greater than 18 and less than 60 years; BMI less than 50; ASA equal to or less than 3; Intraoperative lidocaine infusion time up to 4 hours; no sensitivity to lidocaine; no heart diseases; no liver diseases; no kidney diseases; no psychiatric diseases; Avoiding the use of alcohol and drugs addiction
Exclusion criteria: Withdraw from the study; Intraoperative lidocaine infusion time more 4 hours; conversion laparoscopy to laparotomy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat highway, next to Milad Hospital

City

Tehran

Postal code

Approval date

2014-12-03, 1393/09/12

Ethics committee reference number

4273/105/93/3

Health conditions studied

1

Description of health condition studied

Relation between effect of intravenous infusion of lidocaine during and after surgery on pain and nausea-vomiting in Stomach Bypass with Laparoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

At zero, half an hour, one and six and twelve and twenty-four hours

Method of measurement

V.A.S

2

Description

Nausea-vomiting

Timepoint

At zero, half an hour, one and six and twelve and twenty-four hours

Method of measurement

Asking of patient

3

Description

Systolic blood pressure

Timepoint

At time zero, half an hour and one hour after the operation

Method of measurement

Mercury sphygmomanometer

4

Description

Diastolic blood pressure

Timepoint

At time zero, half an hour and one hour after the operation

Method of measurement

Mercury sphygmomanometer

5

Description

Heart Rate count

Timepoint

At time zero, half an hour and one hour after the operation

Method of measurement

Pulse Rate count

Secondary outcomes

empty

Intervention groups

1

Description

Intravenous lidocaine infusion at doses of 1 mg /kg/hour

Category

Treatment - Drugs

2

Description

Intravenous lidocaine infusion at doses of 2 mg /kg/hour

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasool (S) Educational-Therapeutic Centre

Full name of responsible person

Dr. A.E Abedian

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyyed Ali Javad Mousavi, MD

Street address

Shahid Hemmat Highway, next to Milad Hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Dr. AE Abedian

Position

Assistant of Anesthesiology

Other areas of specialty/work

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Web page address**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