

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Impact of IV Lidocaine on post laparotomic ileus

Protocol summary

Summary

This study is a double-blind randomized clinical trial (RCT). Ileus is a common problem in postoperative period which complicates many of abdominal operations. Lower rates of ileus in Spinal or Epidural anesthesia comparing with General anesthesia made the hypothesis that the systemic absorption of Lidocaine or other local anesthetic agents, may be the cause. So 62 patients which had undergone laparotomies due to various reasons, were divided randomly in two groups, as Lidocaine receivers or Controls. The bolus dose of Lidocaine or placebo were injected intravenously at extubation time. The dose of Lidocaine was 1.5mg/kg and then continued with 1mg/kg/hour for 24 hours. Data were analysed by SPSS 16.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061213656N1**

Registration date: **2013-07-07, 1392/04/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-07, 1392/04/16

Registrant information

Name

Seyed Muhammad Mehdi Ghaffari Hamedani

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 32 07838

Email address

muhammadghaffari@irimc.org

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of IV Lidocaine on post laparotomic ileus

Public title

Impact of IV Lidocaine on post laparotomic ileus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients undergoing laparotomy

Exclusion criteria: history of substance abuse, loss of consciousness, dementia, resection and anastomosis of GI during surgery, presence of chemical or fecal peritonitis as the cause of laparotomy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

48175-688

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

89-171

Health conditions studied

1

Description of health condition studied

Ileus

ICD-10 code

K56.0

ICD-10 code description

Paralytic ileus

Primary outcomes

1

Description

Gas passage or defecation

Timepoint

Postoperative period

Method of measurement

postoperative questionnaire

Secondary outcomes

1

Description

Nausea

Timepoint

Postoperative period

Method of measurement

Postoperative quistionnaire

2

Description

Vomiting

Timepoint

Postoperative period

Method of measurement

Postoperative quistionnaire

3

Description

Score of pain

Timepoint

Postoperative period

Method of measurement

Postoperative quistionnaire

4

Description

Appetite

Timepoint

postoperative period

Method of measurement

postoperative quistionnaire

5

Description

starvation

Timepoint

postoperative period

Method of measurement

postoperative quistionnaire

Intervention groups

1

Description

bolus dose of intravenous Lidocaine 1.5mg/kg and following by maintenance dose of Lidocaine 1mg/kg/h

Category

Prevention

2

Description

bolus dose of intravenous normal saline 1.5cc/kg and following by maintenance dose of normalsaline 1cc/kg/h

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini General Hospital

Full name of responsible person

Seyed Muhammad Mehdi Ghaffari Hamedani, MD

Street address

Surgery department of Imam Khomeini Hospital

City

Sari

2

Recruitment center

Name of recruitment center

Boali Sina Hospital

Full name of responsible person

Seyed Muhammad Mehdi Ghaffari Hamedani, MD

Street address

Surgery department of Imam Khomeini Hospital

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmad Ali Enayati

Street address

Mazandaran university of medical sciences, Moallem Square, Sari, Iran Sari Mazandaran Iran, Islamic Republic Of

City

Sari

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 of Mazandaran 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**

Mazandaran University Of Medical Sciences

Full name of responsible person

Seyed Muhammad Mehdi Ghaffari Hamedani

Position

General & digestive surgeon

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

Surgery department of Imam Khomeini hospital

City

Sari

Postal code**Phone**

+98 26 2225 6329

Fax

+98 15 1225 6329

Email

muhammadghaffari@irimc.org;

ghaffari99@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mazandaran University Of Medical Sciences

Full name of responsible person

Seyed Muhammad Mehdi Ghaffari Hamedani

Position

General & digestive surgeon

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

Surgery department of Imam Khomeini hospital

City

Sari

Postal code**Phone**

+98 15 1225 6329

Fax

+98 15 1225 6329

Email

muhammadghaffari@irimc.org;

ghaffari99@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Mazandaran University Of Medical Sciences

Full name of responsible person

Seyed Muhammad Mehdi Ghaffari Hamedani

Position

General & digestive surgeon

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

Surgery department of Imam Khomeini hospital

City

Sari

Postal code**Phone**

+98 15 1225 6329

Fax

+98 15 1225 6329

Email

muhammadghaffari@irimc.org;

ghaffari99@yahoo.com

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