

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Post-surgical analgesic efficacy of mgso4 versus lignocaine with acetaminophen in asthmatic patients

Protocol summary

Study aim

Compare the analgesic efficacy of magnesium sulfate versus lignocaine with intravenous acetaminophen in asthmatic patients undergoing laparoscopic cholecystectomy.

Design

The patients were Group into M (n=55) receiving IV MgSO₄ and IV Acetaminophen and Group L (n=55) IV Lignocaine with IV Acetaminophen. Variables measured were per-operative mean heart rate, mean arterial pressure, time to first rescue analgesia, total dose of analgesia required in the next 24 hours post-surgery, and median pain scores at 1-, 3- and 6-hour intervals.

Settings and conduct

This quasi-experimental study was carried out at the Department of Anesthesiology, Combined Military Hospital, Rawalpindi from Jun 2023-Dec 2023.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient undergoing laparoscopic cholecystectomy which included all ASA-I and II patients diagnosed with asthma by spirometry pre- and post-bronchodilator therapy. Exclusion criteria: included patients with major cardiac or respiratory disease, low ejection fraction, unoptimized for hypertension or diabetes, patients with cholecystitis, patients allergic to acetaminophen, MgSO₄, lignocaine or nalbuphine, patient with history of asthma exacerbation requiring admission in the last 8 weeks, patients on oral or intravenous steroids for asthma and patients unwilling to be included in the study.

Intervention groups

patients were divided into two groups. Patients in Group M received intravenous MgSO₄ with intravenous acetaminophen. Patients in Group L received intravenous lignocaine with intravenous acetaminophen.

Main outcome variables

heart rate, mean arterial pressure, time to first rescue analgesia, total dose of analgesia required in the next 24 hours post-surgery, and median pain scores at 1-, 3- and

6-hour intervals.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231124060161N2**

Registration date: **2024-05-04, 1403/02/15**

Registration timing: **retrospective**

Last update: **2024-05-04, 1403/02/15**

Update count: **0**

Registration date

2024-05-04, 1403/02/15

Registrant information

Name

Saddam Hussain

Name of organization / entity

Combined military hospital rawalpindi

Country

Pakistan

Phone

+92 344 9017071

Email address

saddam13315@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-20, 1402/05/29

Actual recruitment start date

2023-02-20, 1401/12/01

Actual recruitment end date

2023-08-20, 1402/05/29

Trial completion date

2023-08-20, 1402/05/29

Scientific title

Post-surgical analgesic efficacy of mgso4 versus lignocaine with acetaminophen in asthmatic patients

Public title

Post-surgical analgesic efficacy of mgso4 versus lignocaine with acetaminophen in asthmatic patients

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

all ASA-I and II patients diagnosed with asthma by spirometry pre- and post-bronchodilator therapy with confirmation of reversibility presenting to the surgical department for elective laparoscopic cholecystectomy compliant and optimized on treatment.

Exclusion criteria:

major cardiac or respiratory disease low ejection fraction unoptimized for hypertension or diabetes patients with cholecystitis, patients allergic to acetaminophen, MgSO4, lignocaine or nalbuphine patient with a history of asthma exacerbation requiring admission in the last 8 weeks. patients on oral or intravenous steroids for asthma patients unwilling to be included in the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

More than 1 sample in each individual

Actual sample size in each individual: **70**

Sample size came out to be 70 patients. we included 110 patients in our study after randomization. The method of randomization was non-probability consecutive sampling via lottery method.

Randomization (investigator's opinion)

Not 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**

ethical committee review board

Street address

CMH road rawalpindi

City

rawalpindi

Postal code

46000

Approval date

2023-12-20, 1402/09/29

Ethics committee reference number

499

Health conditions studied**1****Description of health condition studied**

pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes**1****Description**

analgesia

Timepoint

24hrs after first analgesics dose.

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes**1****Description**

Hypotension

Timepoint

1,3,6 hours.

Method of measurement

cardiac monitor, sphygmomanometer

2**Description**

Respiratory depression

Timepoint

1,3,6 hours

Method of measurement

pulse oximetry, cardiac monitor

3

Description

nausea

Timepoint

1,3,6 hours

Method of measurement

Visual assessment and patient complaints.

4

Description

vomiting

Timepoint

1,3,6 hours

Method of measurement

Clinical assessment, patient complaints.

Intervention groups

1

Description

Intervention group 1: Patients in the intervention Group received intravenous MgSO₄ at 50 mg/kg diluted in 100 ml of normal saline over 15 minutes with intravenous acetaminophen 15 mg/kg over 15 minutes before induction of anesthesia followed by an infusion of intravenous magnesium sulfate at 25 mg/kg/hr per-operatively.

Category

Treatment - Drugs

2

Description

intervention group 2: Patients in the control Group received intravenous lignocaine at a dose of 1.5 mg/kg with intravenous acetaminophen 15 mg/kg over 15 minutes before the induction of anesthesia followed by an infusion of intravenous lignocaine at 2 mg/kg/hr per-operatively.

Category

Treatment - Drugs

3

Description

Control group: received nothing.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

CMH rawalpindi

Full name of responsible person

Combined Military Hospital.

Street address

CMH road

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Phone

+92 51 9273423

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saddam133@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

CMH Rawalpindi

Full name of responsible person

Saddam Hussain

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saddam133work@outlook.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

CMH Rawalpindi

Proportion provided by this source

100

Public or private sector

Private

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**

CMH Rawalpindi

Full name of responsible person

Saddam Hussain

Position

Registrar

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Saddam Hussain
Position
registrar
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact

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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