Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
City
Rawalpindi
Postal code
46000
Phone
+92 51 9273423
Email
saddam133@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
CMH Rawalpindi
Full name of responsible person
Saddam Hussain
Street address
cmh road
City
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Postal code
46000
Phone
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Email
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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Email
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Person responsible for scientific 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 updating data

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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