Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of intravenous Magnesium Sulphate combined with Acetaminophen versus intravenous Nalbuphine in COPD patients undergoing elective Cholecystectomy

Protocol summary

Study aim

The objective of this study is to compare the analgesic efficacy of non-opioid anesthesia (NOA) using intravenous magnesium sulphate combined with intravenous acetaminophen versus intravenous nalbuphine in chronic obstructive pulmonary disease patients undergoing elective laparoscopic cholecystectomy.

Design

A Non-Blinded randomized control trial, Single center study with two intervention groups including a sample size of 110 patients

Settings and conduct

Quasi experimental Non-Blinded Study was conducted in Department of Anaesthesia Combined Military Hospital Rawalpindi. The Method of Sampling was Non-randomized trial with Sample size of 110 (55 in each of the two groups)

Participants/Inclusion and exclusion criteria

Inclusion criteria included all American Society of Anaesthesiology Class II and III patients of Chronic obstructive pulmonary disease diagnosed by pulmonary function test with optimized diasease between ages 45-70 years presenting in the general surgical department for elective cholecystectomy for cholelithiasis. 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, Magnesium Sulphate (MgSO4) or Nalbuphine and patients unwilling to be included in the study.

Intervention groups

The study method included all patients as per the inclusion criteria furnished. The patients were divided into Group M (n=55) receiving Magnesium Sulphate (MgSO4) and Acetaminophen and Group N (n=55) receiving nalbuphine.

Main outcome variables

Primary outcome variables measured were intraoperative mean heart rate, mean arterial pressure, time to rescue analgesia and median pain scores at 1, 3 and 6 hour intervals. Secondary outcome variables were the incidence of hypotension, respiratory depression, nausea and vomiting between both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230819059186N2**
Registration date: **2024-01-21, 1402/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-21, 1402/11/01**
Update count: **0**

Registration date

2024-01-21, 1402/11/01

Registrant information

Name

Syed Aqib Ali Shah

Name of organization / entity

Combined Military Hospital Rawalpindi Punjab pakistan

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-08-02, 1402/05/11
Expected recruitment end date
2024-02-02, 1402/11/13
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of intravenous Magnesium Sulphate combined with Acetaminophen versus intravenous Nalbuphine in COPD patients undergoing elective Cholecystectomy

Public title
Comparison of intravenous Magnesium Sulphate combined with Acetaminophen versus intravenous Nalbuphine in COPD patients undergoing elective Cholecystectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Included all ASA-II and III patients of COPD diagnosed by PFTs (pulmonary function test) with optimized diasease Patient with age between 45-70 years presenting in the general surgical department for elective cholecystectomy for cholelithiasis.
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 or nalbuphine and patients unwilling to be included in the study.
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
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 institutional review board Combined Military Hospital Rawalpindi
Street address
26 No Road Saddar Rawalpindi
City
Rawalpindi
Postal code
46000
Approval date
2023-08-24, 1402/06/02
Ethics committee reference number
430

Health conditions studied

1

Description of health condition studied
Analgesic efficacy of Non opioid Anaesthesia (NOA)
ICD-10 code
Z82.5
ICD-10 code description
Family history of Asthma and other Chronic lower respiratory diseases

Primary outcomes

1

Description
Per-Operative Mean Heart Rate
Timepoint
Mean heart rate (HR) was observed between both groups per-operatively 15 minutes after surgical incision (HR 1) and 15 minutes before extubation (HR 2)
Method of measurement
Standard Monitoring with ECG leads attached to the patients

2

Description
Per-Operative Mean Arterial Pressure
Timepoint
Mean arterial pressure (MAP) were observed between both groups per-operatively 15 minutes after surgical incision (MAP 1) and 15 minutes before extubation (MAP 2)
Method of measurement
Non-Invasive Blood Pressure Measurement

3

Description
Time to Rescue Analgesia
Timepoint
Once the pain score on the visual analog scale (VAS) were above 4
Method of measurement
Visual analog scale (VAS)

4

Description
Post-Operative Analgesic efficacy
Timepoint
Observed at 1,3 & 6 hrs
Method of measurement
Median Pain Score at 1,3 & 6 hrs and Visual analog scale (VAS)

Secondary outcomes

1

Description
Post-Operative Respiratory depression
Timepoint
Observed 6hrs post operatively
Method of measurement
Clinical assessment of Respiratory Rate, Pattern of breathing and Oxygen Saturation was observed using Pulse Oximetry

Intervention groups

1

Description
Intervention group 1: Patients in Group M 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
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in Group N received Nalbuphine 0.15 mg/kg diluted in 100 ml normal saline over 15 minutes before induction.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital Rawalpindi Pakistan
Full name of responsible person
Syed Aqib Ali Shah
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26 No saddar Rawalpindi
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Combined Military Hospital Rawalpindi Pakistan
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
Combined Military Hospital Rawalpindi Pakistan
Full name of responsible person
Syed Aqib Ali Shah

Position
Resident Anaesthesiology
Latest degree
Medical doctor
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