

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 disease 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

Phone

+92 51 9273426

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aqibalishahsyed@gmail.com

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 disease 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined Military Hospital Rawalpindi Pakistan

Full name of responsible person

Syed Aqib Ali Shah

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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 scientific inquiries**Contact****Name of organization / entity**

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Position

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Other areas of specialty/work

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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