

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 (MgSO<sub>4</sub>) 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 (MgSO<sub>4</sub>) 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

##### Email address

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

#### **Street address**

26 No saddar Rawalpindi

#### **City**

Rawalpindi

#### **Postal code**

46000

#### **Phone**

+92 335 5562605

#### **Email**

aqibalishahsyed@gmail.com

#### **Web page address**

<https://numspak.edu.pk/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Combined Military Hospital Rawalpindi Pakistan

##### **Full name of responsible person**

Syed Aqib Ali Shah

##### **Street address**

26 No Saddar Rawalpindi

##### **City**

Rawalpindi

##### **Postal code**

46000

##### **Phone**

+92 335 5562605

##### **Email**

aqibalishahsyed@gmail.com

##### **Web page address**

<https://numspak.edu.pk/>

#### **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

**Street address**

No 26 saddar Rawalpindi

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 51 9273426

**Email**

aqibalishahsyed@gmail.com

**Web page address**

<https://numspak.edu.pk/>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Combined Military Hospital Rawalpindi Pakistan

**Full name of responsible person**

Dain bin khalid

**Position**

Resident Anaesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

No 26 Saddar Rawalpindi

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 51 9273426

**Email**

aqibalishahsyed@gmail.com

**Web page address**

<https://numspak.edu.pk/>

**Person responsible for updating data****Contact****Name of organization / entity**

Combined Military Hospital Rawalpindi Pakistan

**Full name of responsible person**

Munim ilyas

**Position**

Resident Anaesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

No. 26 Saddar Rawalpindi Pakistan

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 51 9273426

**Email**

aqibalishahsyed@gmail.com

**Web page address**

<https://numspak.edu.pk/>

**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