

15-Feb-26

COVER LETTER

To
Protocol Registration and Results System (PRS) Team
ClinicalTrials.gov
U.S. National Library of Medicine

Subject: Clinical Trial Registration Submission

Dear Sir/Madam,

I am submitting our study titled “**Comparison of Dexmedetomidine and Dexamethasone for the Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Laparoscopic Cholecystectomy: A Randomized Controlled Trial**” for registration on ClinicalTrials.gov.

This is a prospective, double-blind, randomized controlled trial to be conducted at Patel Hospital, Karachi, Pakistan. The study aims to compare the effectiveness of intravenous dexmedetomidine and dexamethasone in preventing postoperative nausea and vomiting in adult patients undergoing elective laparoscopic cholecystectomy.

The protocol follows Good Clinical Practice guidelines. Ethical approval will be obtained from the Ethical Review Committee of Patel Hospital and CPSP. Written informed consent will be obtained from all participants.

We kindly request registration of this trial and assignment of a ClinicalTrials.gov Identifier. Please let us know if further information is required.

Sincerely,
Dr. Marium Rafiq
Principal Investigator
Patel Hospital, Karachi, Pakistan

INFORMED CONSENT

Project Information	
Project Title: Comparison of dexmedetomidine and dexamethasone for the prevention of postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy; A randomized controlled trial	ERC Ref No:
Principal Investigator: Dr. Marium Rafiq	Organization: Patel Hospital
Location: Karachi	Phone: 03406880873

1. PURPOSE OF THIS RESEARCH STUDY

You are being asked to participate in a research study designed to compare dexmedetomidine and dexamethasone for the prevention of postoperative nausea and vomiting PONV in patients undergoing laparoscopic cholecystectomy

2. PROCEDURES

As a study participant, you will received one of the study drugs at the time of induction of anaesthesia and postoperatively, the score of PONV will be evaluated using the PONV scaling score at the following intervals: on arrival in the PACU (T0), at 4 h (T1), at 12 h (T2) and at 24 h (T3) postoperatively.

3. POSSIBLE RISKS OR DISCOMFORT

Not applicable

4. POSSIBLE BENEFITS

As a research participant, you will not get any benefit individually from this study. This study has broader objectives which will be helpful for the healthcare profession in longer run.

5. FINANCIAL CONSIDERATIONS

You are not expected to bear any cost for participation in our research survey, neither are there any monetary benefits you may be entitled to.

6. AVAILABLE TREATMENT ALTERNATIVES

Not applicable

7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

Not applicable.

8. CONFIDENTIALITY

Our research protocol has been approved by the Ethical Review Committee of Patel Hospital, Karachi. For this approval, we have made every effort to ensure the confidentiality of research data collected from all our participants in this survey. The information collected will only be stored with the principal investigator and co-investigators. Any result generated will be presented on a collective basis, and will not contain your name or any other personal details.

9. TERMINATION OF RESEARCH STUDY

You are free to choose whether or not to participate in this study. There will be no penalty on you if you choose not to participate. You may also choose to discontinue your participation at any time during the interview. Please note, this is a one-time course of study only and there will be no follow up visits.

10. AVAILABLE SOURCES OF INFORMATION

Any further questions you have about this study will be answered by the Principal Investigator:

Name: _____

Phone Number: _____

Any questions you may have about your rights as a research subject will be answered by:

Name: _____

Phone Number: _____

If applicable:

In case of a research-related emergency, call:

Day Emergency Number: _____
Night Emergency Number: _____

11. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study.
I understand that I will receive a copy of this form.

Participant Name (Printed or Typed): _____

Participant Signature: _____

Date: _____

Principal Investigator Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____