UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: Quantitative Analysis of Postoperative Analgesia Following Abdominal Surgery Using Repeated Time-to-Event Modelling of Rescue Analgesic Administration

Version No: 1.0

Version Date: 09 July 2026

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

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1. What is the purpose of this study?

The purpose of this study is to better understand the pattern of pain-relief medicine use after abdominal surgery. Specifically, this study will look at how often patients need rescue pain medicine, such as morphine given through a patient-controlled analgesia pump, during the first 48 hours after surgery. The information collected will be used to develop a mathematical model that may help doctors better understand postoperative pain and improve future pain management.

2. Why is this study important?

Pain after abdominal surgery is common, even when standard pain-relief treatment is given. Some patients may still experience moderate or severe pain and may need repeated doses of rescue pain medicine. Current ways of measuring pain medicine use often look only at the total amount of medicine used or the time to the first rescue dose. These methods may not fully describe the repeated and changing pattern of pain after surgery. This study is important because it may help doctors identify when patients are more likely to need rescue pain medicine and support more personalised pain treatment in the future.

3. What type of study is this?

This is a single-center prospective observational cohort study. This means that the research team will observe and record information from patients undergoing elective abdominal surgery. The study will not change your usual clinical care

or treatment.

4. What is the procedure that is being tested? (If applicable)

There is no new procedure, drug, or treatment being tested in this study. You will receive the usual postoperative pain management provided by the clinical team. The study only involves collecting information about your pain scores, pain medicine use, and related clinical data during the first 48 hours after surgery.

5. Does the investigatory product contain culturally sensitive ingredients e.g.: bovine or porcine? (If applicable)

Not applicable. This study does not involve any investigational product.

6. Why have I been invited to participate in this study?

You have been invited because you are an adult patient scheduled to undergo elective abdominal surgery under general anaesthesia, and you are expected to stay in the ward or high-dependency unit for at least 48 hours after surgery. You are also able to understand the study information, provide written consent, and report your pain using a numerical pain score.

7. Who should not participate in the study?

You should not participate if you are below 18 years old or above 75 years old, are not undergoing elective abdominal surgery under general anaesthesia, or are unable to give written informed consent. You should also not participate if you have severe liver or kidney impairment, known allergy or hypersensitivity to morphine or opioid pain medicines, regular opioid use for four weeks or more before surgery, a documented substance use disorder, or a condition that prevents reliable pain scoring, such as significant cognitive impairment, delirium, language barrier, or communication difficulty.

8. Can I refuse to take part in the study?

Yes. Participation in this study is entirely voluntary. You may choose not to take part, and your decision will not affect the medical care, treatment, or benefits that you are entitled to receive. Your doctors and nurses will continue to care for you as usual.

9. What will happen to me if I take part?

If you agree to take part, the research team will ask you to sign a consent form before collecting study data. Your usual surgery, anaesthesia, and postoperative pain treatment will continue as planned. During the first 48 hours after surgery, the research team will collect information from your medical records and pain management records. This includes your age, sex, weight, height, type of surgery, anaesthesia details, pain scores, pain medicine doses, timing of successful and unsuccessful patient-controlled analgesia demands, and any side effects such as nausea, vomiting, itchiness, sedation, breathing rate, and oxygen level. You may also be asked to record your pain score before pressing the pain-relief button, according to the instructions given by the clinical team.

10. How long will I be involved in this study?

You will be involved in the study for the first 48 hours after your surgery. No additional study visits are required after this 48-hour observation period.

11. What are the possible disadvantages and risks?

This study involves minimal additional risk because it does not introduce any new treatment, procedure, blood test, or experimental medicine. You will receive the usual postoperative care provided by your clinical team. Some inconvenience may occur because the research team will collect pain scores and related information during the first 48 hours after surgery. The usual risks of opioid pain medicine, such as nausea, vomiting, sleepiness, itchiness, constipation, or slowed breathing, are related to standard clinical care and will be monitored by the clinical team.

12. What are the possible benefits to me?

You may not receive any direct personal benefit from taking part in this study. However, your pain scores and side effects will be observed and recorded carefully during the study period. The information gained may help improve understanding of postoperative pain patterns and may benefit future patients undergoing abdominal surgery.

13. Who will have access to my medical records and research data?

Members of the research team, authorised study personnel, the Medical Research Ethics Committee, regulatory authorities, and authorised representatives of Universiti Malaya Medical Centre may access your medical records and research data when necessary for study monitoring, audit, or verification. Access will be limited to information relevant to this study.

14. Will my records/data be kept confidential?

Yes. Your personal information and research data will be kept confidential. You will be assigned a study identification number, and this number will be used in the research database instead of your name whenever possible. Any publication or presentation from this study will not include information that can identify you personally. Study data will be stored securely and accessed only by authorised personnel.

15. What will happen to any samples I give? (If applicable)

This study involves no additional tests, examinations, or blood samples.

16. What will happen if I don’t want to carry on with the study?

If you decide to withdraw from the research project, please notify a member of the research team before you withdraw. This will allow the research team or research supervisor to discuss any health risks or special requirements linked to withdrawing.

Please be aware that data collected up to the time you withdraw may still be used as part of the research project results. The study doctor and research staff will not collect additional personal information about you after withdrawal, but

personal information already collected may be retained to ensure that the research results can be measured properly and to comply with legal and regulatory requirements. If you do not want your previously collected data to be used, you should inform the research team.

17. What if relevant new information about the procedure/drug/ intervention becomes available? (If applicable)

Not applicable. This study does not involve a new procedure, investigational drug, or intervention.

18. What happens when the research study stops? (If applicable)

Your participation in the study will end.

19. What will happen to the results of the research study?

The results of this study may be presented at scientific meetings, published in medical journals, or used for academic and research purposes. Your identity will not be revealed in any report, presentation, or publication. The study results may help improve understanding of postoperative pain and guide future research on pain management after abdominal surgery.

20. Will I receive compensation for participating in this study?

You will not receive any compensation or payment for participating in this study. There will also be no additional study-related cost to you.

21. Who funds this study?

If no external funding has been obtained, this study is conducted as an investigator-initiated research project with no external commercial sponsor.

22. Who should I contact if I have additional questions/problems during the study?

Name of investigator: Dr Teoh Tsyr Xiang
Affiliation: Department of Anesthesiology, Faculty of Medicine, Universiti Malaya
Telephone number: 017-4540608

Name of investigator: Assc. Prof Dr Chaw Sook Hui
Affiliation: Department of Anesthesiology, Faculty of Medicine, Universiti Malaya
Telephone number: 012-326 0566

23. Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number: 03-7949 3209/2251