Lianyungang First People's Hospital AF/FJ-LLWYH-04/01.0

informed consent

Study Title: Correlation Analysis Between Intraoperative Mean Arterial Pressure Variability and Postoperative Fatigue in Patients Undergoing Laparoscopic Abdominal Surgery
Version: V2.0 Date: October 15,2025
Informed Consent Form Version Number: V2.0 Version Date: October 15,2025
Research institution: Lianyungang First People's Hospital
Principal Investigator (Responsible Investigator): Zhang Xiaobao

You will be invited to participate in a clinical study. This informed consent provides you with information to help you decide whether to participate in this clinical study. Please read it carefully, and if you have any questions, please consult the investigator responsible for the study.
Your participation in this study is voluntary. This study has been reviewed and approved by the Institutional Review Board (IRB) of our research institution.
1. Research Objective: With the increasing number of surgical procedures, laparoscopic surgery has become a common approach for major abdominal operations due to its minimal invasiveness and rapid recovery. However, many patients experience a condition termed "postoperative fatigue syndrome" after surgery, characterized by extreme fatigue, weakness, poor sleep, and difficulty concentrating. This not only impairs recovery but may also prolong hospital stays and even lead to other complications. Although studies have explored methods to alleviate postoperative fatigue (e.g., pharmacological interventions or massage), no particularly effective approaches have been established to date. Research has suggested that blood pressure stability may be associated with fatigue. Significant blood pressure fluctuations may indicate poor physiological regulation and increased susceptibility to fatigue. This study aims to investigate whether intraoperative blood pressure fluctuations correlate with postoperative fatigue. If a correlation is found, future clinicians may utilize blood pressure control during surgery to help patients reduce fatigue and accelerate recovery.
2. Research Process: The entire research process will be conducted as follows: We plan to invite approximately 500 eligible patients who have undergone such surgeries at Lianyungang First People's Hospital to participate. Prior to the study commencement, we will provide you with a detailed explanation of all details, and you will sign an informed consent form on a fully voluntary basis. After participation, you will undergo a preoperative visit where we will record your basic health information and current fatigue perception. During the surgery, no additional procedures will be performed; instead, your blood pressure data will be automatically and continuously monitored through standard anesthesia monitoring equipment, which will not cause any additional discomfort or risk. During your postoperative hospitalization, we will visit your bedside on the first, third, and seventh days, and you will be

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asked to spend a few minutes completing two simple questionnaires to primarily assess your fatigue level and recovery quality. Please rest assured that this study does not require any additional invasive examinations, and all data will be derived from routine medical procedures. More importantly, all participants will receive strictly standardized anesthesia and surgical protocols and will not be assigned to any different treatment groups. We will only analyze the natural variations in blood pressure fluctuations after surgery to explore potential associations between blood pressure stability and postoperative fatigue. Your participation will provide valuable information for improving the postoperative recovery experience of future patients. If you agree to participate in this study, we will conduct a detailed communication with you or your family members, introducing the relevant details of the study. Additionally, we request that you provide information related to the disease, including the disease course, family history, previous medical visits, and any prior examination results. Each participant will be assigned a unique number and a medical record will be established.

3. Potential Risks and Discomforts: Participation in this study does not pose significant additional health risks. As this is primarily an observational study, we will not alter your established anesthesia or surgical protocol, nor will we perform any additional invasive procedures. The blood pressure data analyzed in the study are derived from routine medical monitoring during your surgery (e.g., arterial pressure measurement), and no additional needle insertions or increased discomfort will be incurred.

The primary inconvenience of the study lies in the time commitment required. We will provide you with a detailed explanation of the study and obtain your consent prior to the procedure, which may take approximately 15-20 minutes. Additionally, during your postoperative recovery period, we will visit you on the first, third, and seventh days to administer questionnaires regarding fatigue and recovery quality, each taking about 10-15 minutes. This may cause brief disruptions during your rest periods.

Regarding information confidentiality, we will collect certain medical data and questionnaire responses from you. We pledge that all information will be strictly confidential and used solely for the purposes of this study. Your name and other personal identifiers will be converted into codes, and no personally identifiable information will appear in the research report.

Finally, although the procedure of this study carries extremely low inherent risks, any surgical and anesthetic interventions inherently involve routine risks unrelated to this study, which will be thoroughly discussed with you by your attending physician. All your medical rights and interests during the study process will remain unaffected, and you retain the right to withdraw from the study at any time without compromising your entitlement to subsequent medical services.

4. Expected Benefits: Participation in this study may not provide you with direct therapeutic benefits, as the primary objective of this research is to observe and collect information to advance medical knowledge. However, your involvement will provide us with extremely

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valuable insights, enabling a deeper understanding of the causes of postoperative fatigue. The data you contribute may, in the future, assist physicians in optimizing intraoperative blood pressure management strategies, thereby reducing postoperative fatigue in patients undergoing similar procedures, accelerating their recovery process, and enhancing their surgical experience.

5. Privacy Protection: If you decide to participate in this study, your participation and personal data during the study will be kept confidential. The study physicians and other researchers will use your medical information for the research. This information may include your name, address, telephone number, medical history, and information obtained during your study visit. Your records will be stored in a locked file cabinet and accessible only to the researchers. To ensure the study is conducted in accordance with regulations, government regulatory authorities or members of the ethics review committee may, when necessary, access your personal data at the study site as required. When the study results are published, no personal information about you will be disclosed.

6. Compensation

If you are harmed as a result of participating in this study: you may receive free treatment and appropriate compensation in the event of any harm related to the clinical study.

7. Rights of Subjects and Investigators

You may opt out of this study or request to withdraw at any time by notifying the investigator. Your data will not be included in the study results, and your medical benefits and entitlements will not be affected accordingly.

If additional treatment is required, if you fail to comply with the study protocol, if study-related injury occurs, or for any other reason, the study physician may terminate your participation in this study.

You may access relevant information and updates regarding this study at any time. We will promptly notify you of any new safety information related to this study. If you have questions about the study, experience any discomfort or injury during the research process, or have inquiries regarding the rights and interests of participants, please contact Xue Xiang at 13815375967.

If you have any questions or concerns regarding the rights and health benefits of participating in this study, please contact the Institutional Ethics Committee at the following telephone number: 0518-85767557

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Informed Consent Form Signature Page

I have read this informed consent form.

I had the opportunity to ask questions and all of them were answered.

I understand that participation in this study is voluntary.

I may opt out of this study or withdraw at any time by notifying the investigator without facing discrimination or retaliation, and my medical treatment and rights will not be affected.

If I require additional treatment, fail to adhere to the study protocol, sustain study-related injuries, or for any other reason, the study physician may terminate my participation in this study.

I will receive a signed copy of the informed consent form.

Subject Name: _____

Subject's signature: _____

date ： _____Year _____ Month _____ Day

I have accurately informed the subject of this document, and he/she has accurately read the informed consent form and had the opportunity to ask questions.

Name of the researcher: _____

Researcher's signature: _____

date ： _____Year _____ Month _____ Day

(Note: If the subject is illiterate, a witness's signature is required; if the subject lacks legal capacity, a proxy's signature is required.)