Informed Consent Form·Notification Page

Program name: Comparison of the analgesic efficacy of the combination of transversus abdominis plane block and rectus sheath block in relation to erector spinae plane block after patients undergoing laparoscopic liver resection surgery

NCT number:
Date of applicant: September 20, 2023

Informed Consent Form·Notification Page

Dear subjects:

We will invite you to participate in a study "Comparison of the analgesic efficacy of the combination of transversus abdominis plane block(TAPB) and rectus sheath block(RSB) in relation to erector spinae plane block(ESPB) after patients undergoing laparoscopic liver resection surgery". The study protocol has been approved by the Medical Ethics Committee of Tongji Hospital affiliated to Tongji Medical College of Huazhong University of Science and Technology and agreed to conduct clinical research.

Before you decide whether to participate in this study, please read the following content as carefully as possible. It can help you understand the study and why it is being conducted, the procedure and duration of the study, and the potential benefits, risks and discomfort that participating in the research may bring to you. If you are willing, you can also discuss it with your relatives and friends, or ask a doctor for an explanation to help you make a decision.

If you are currently participating in other clinical study, please be sure to inform your research physician or investigator. Thank you for your support of this study.

1.Why is this study conducted?

1.1 Disease burden and the current status of the treatment

According to the 2022 guidelines for perioperative care for liver surgery, implementing Enhanced Recovery After Surgery(ERAS) in liver surgery may improve postoperative outcomes. Compared with open hepatectomy, laparoscopic hepatectomy has the advantages of less postoperative hospitalization time and lower complication rates, which is recommended in well-trained teams and clinically appropriate situations. The peak pain of postlaparoscopic surgery mainly occurs in the first 24 hours, so it is particularly important to find an appropriate way to relieve pain.

Regional anesthesia is an important component of multimodal analgesia, and TAPB, RSB, and ESPB are widely used in abdominal surgery. TAPB blocks the sensory nerves in the anterior lateral abdominal wall (T6-L1), RSB blocks the terminal branches of the 9th, 10th and 11th intercostal nerves between the internal oblique and transversus abdominis muscles, ESPB acts on the ventral and dorsal branches of the spinal nerve and further promotes visceral analgesia by blocking sympathetic nerves. Ultrasound-guided nerve block can visualize the target area, which can achieve the

purpose of more precise and safer nerve block, and provide great help for postoperative analgesia. Postoperative analgesia and recovery effects of ESPB had not been compared with TAPB combine with RSB in patients undergoing laparoscopic liver resection surgery.

1.2 Study Purpose

To compare the postoperative analgesia and recovery effect of TAPB combined with RSB and ESPB in patients undergoing laparoscopic hepatectomy.

2. Who will be invited to join the study?

1) ASA grades I-II
2) age 18~70 years old
3) BMI 19～28kg/m2
4) patients undergoing elective laparoscopic partial liver resection

3.Participating units and the number of expected inclusion in the study

This study will be conducted in the Tongji Hospital affiliated to Tongji Medical College of Huazhong University of Science and Technology and 60 subjects are expected to participate voluntarily.

3. What is required if participating in the study

4.1 Before you are selected in the research, doctor will ask and record your medical history and perform relevant examine.

You are an eligible entrants, you can voluntarily participate in the study and sign an informed consent form.

We will treat you as your wish if you are not willing to participate in this research.

4.2 If you volunteer to participate in the research, the following steps will be followed.

1）All patients were routinely fasted before surgery.

2）After entering the operating room, the VAS score is measured and the QoR-15 patient questionnaire should be filled out.

3）Electrocardiogram (ECG), blood pressure, arterial oxygen saturation (SpO2) is routine monitor; internal jugular venous puncture catheterization under ultrasound guidance after local anesthesia is performed to monitor CVP.

4）You will be randomly assigned to receive ultrasound-guided ESPB under local anesthesia in the experimental group or ultrasound-guided TAPB combined with RSB under local anesthesia in the control group.

5）General anesthesia is routinely induced and tracheal intubation is performed to control respiration.

6）General anesthesia is routinely maintained until the end of surgery. After awakening, the patient is extubated and sent to PACU.

7）The doctor will follow up with you to understand the use of analgesic pump, measure your VAS score and fill out the QoR-15 patient questionnaire after the operation.

4.3 Other matters that require your cooperation

Learning to use VAS to assess the degree of pain and use PCA for pain management after surgery.

4. Possible benefits of participating in the study

You probably already know about your condition and will have routine general anesthesia even if you are not participate in a clinical trial. According to the established protocol, when you are eligible for the trial, your treatment data will be recorded and kept in a more scientifically reliable way. Ultrasound-guided ESPB will provide adequate postoperative analgesia when you are enrolled in the trial group. Whether the analgesia and postoperative recovery effect of TAPB combine with RSB are the same as that of ESPB in patients undergoing laparoscopic hepatectomy, which require the participation of you and other subjects. The clinical results obtained in this study may make a significant contribution to the treatment of patients with the same disease in the future.

You will receive appropriate care and treatment from doctors during your treatment. We have perfect medical facilities to provide you with help and services at any time. In case of adverse reactions related to the trial occur, timely and necessary treatment could be obtained free of charge.

5. Possible adverse effects, risks and discomfort, inconvenience of participating in the study

Definition and reporting system of serious adverse events: nerve blocks carry a risk of local anesthetic poisoning and puncture injury. Any adverse events that occur

to a subject during the study must be determined in nature, severity and relevance to the clinical treatment study, and it should be strictly recorded in the case report form. When serious adverse reactions occurs, they should be handled immediately according to the management procedures of our hospital and reported to the study group within 24 hours.

6.1 Precautions for adverse events

1) Ultrasound-guided nerve block can visualize the puncture needle tips, effectively and greatly reduce the risk of local anesthetic poisoning and puncture injury.

2) Local anesthetic poisoning: strict control the dose of drug, strict intraoperative monitoring. Once local anesthetic poisoning presents, it should be treated immediately according to the treatment procedure of local anesthetic poisoning, such as electrocardiogram monitoring, respiratory tract management, volume control, sedation and anticonvulsion, and the use of corresponding vasoactive drugs.

3) Puncture injury: Performing carefully and discreetly under visualization of ultrasound to ensure that tissue damage is minimized. Once present, surgery may intervene depending on severity.

Doctor will closely monitor your condition to ensure your health, and will truthfully tell you any changes in the course of the study and any newly identified adverse effects.

If you are harmed or have anything unexpected circumstances because of participating in this study, whether it is related to the intervention or not, your doctor will make a judgment and take medical action.

Physicians will try their best to prevent and treat possible harm as a result of this study. If an adverse event occurs during a clinical trial, a committee of medical experts will determine whether it is related to the intervention. Finally, according to the provisions of "Good Clinical Practice" in China, the sponsor will provide the cost of treatment and corresponding economic compensation for trial-related injuries.

eg.【If you experience any discomfort, new changes in your condition, or any Unexpected situation, whether related to the study or not, you should notify your Doctor in time, and he/she will make a judgment and give appropriate medical treatment.】

【During the study period, you need to go to the hospital on time for follow-up andsome examinations,which will take up some of your time and may cause you trouble or inconvenience.】

6. Related costs

7.1 During the study period, you will receive the following free medical treatment

1) two ultrasound examinations of superficial tissues

2) Ultrasound-guided ESPB or ultrasound-guided TAPB combined with RSB

3) Evaluating preoperative and postoperative pain by using visual analogue scale(VAS)

7.2 The other costs related to anesthesia, monitoring and drug will be in the charge of the subjects themselves.

eg.【Doctors will do their best to prevent and treat possible harm as a result of this study. If an adverse event occurs during a clinical trial, a committee of medical experts will determine whether it is related to the study. The trial team will provide treatment costs and financial compensation for trial-related injuries.】

【The treatment and examination required for other diseases you have combined will not be included in the free scope.】

8.Confidentiality of personal information

Your medical records (study charts/CRF, lab tests, etc.) will be preserved completely in the hospital where you are treated. Doctor will record laboratory and other examination results in your medical record. Investigators, ethics committees, and administration will be given access to your medical records but your personal identity will not be disclosed in any public report of the results of this study. We will make every effort to protect the privacy of your personal medical data within legal limits.

According to the ethics of medical research, in addition to personal privacy information, the trial data will be available for public inquiry and sharing, which will be limited to Web-based electronic databases. And ensuring that no personal privacy information will be disclosed.

9.How to get more information?

You can ask any questions about the study at any time and receive relevant answers.

Your doctor will promptly inform you if there is any significant new information that may impact your willingness to continue to participate in this sturdy during the

course of the study.

10.The choice to participate or withdraw from the study is voluntary

Whether to participate in the study is entirely up to your wishes. You can refuse to take part in it or withdraw from the study at any point during the study, which will not influence your relationship with the doctor and your medical care will not be lose in other aspects.

Physicians or investigators may discontinue your participation at any time during the study for your best interests.

If you drop out of the research, for the benefits of your health, you may be asked about your mode of nerve block. If doctors think it is necessary, you may also be asked to undergo a physical examination, physical and chemical examination, which will be beneficial to your health.

If you need any additional treatment because of changes in your condition, you can take other treatment at any time, but please truthfully tell your doctor afterwards.

11. What to do now?

Whether to participate in the research is up to you (and your family). Please ask your doctor pertinent questions if possible before making a decision to join in the study.

Thank you for reviewing the above materials. If you decide to participate in this study, please tell your doctor, who will arrange everything related to the research for you. Please retain this information.

Informed Consent Form . Signature Page

Project title: Comparison of the analgesic efficacy of the combination of transversus abdominis plane block(TAPB) and rectus sheath block(RSB) in relation to erector spinae plane block(ESPB) after patients undergoing laparoscopic liver resection surgery

Undertaking unit: Tongji Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology

Statement of Consent

I have read the above descriptions about the study and have the opportunity to discuss it with physicians and raise questions. All my questions are answered satisfactorily.

I am aware of the risks and benefits that may arise by participating in this study. I understand that participation in this research is voluntary and I confirm that I have ample time to consider it and understand that:

●I can always ask the doctor for more information.

● I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I consent to the ethics committee or the administration having access to my research data.

I will obtain a signed and dated copy of the informed consent.

Finally, I decided to agree to join in the study and promise to follow doctor's advice as much as possible.

Participant’s signature：_____ Date：_____

Cell phoner: _____

I confirm that details of the trial have been explained to the patient, including its rights and possible benefits and risks, and give the patient a signed copy of informed consent.

Investigator's signature：_____ Date：_____

Cell phoner: _____