Title: Effect to Gastrointestinal Barrier Function During Laparoscopic Gastrectomy with Deep vs Moderate Neuromuscular Blockade

NCT number: NCT03782233

Date: 2018-11-04

Informed consent

Dear
Sir/Madam:

We are glad to invite you to participate in the research project 'Effect of different depth of neuromuscular block on intestinal barrier function after laparoscopic gastrectomy' approved by Wu Jieping Medical Foundation. The study will be conducted at the First Affiliated Hospital of Nanjing Medical University (Jiangsu Province Hospital), with an estimated 83 participants. This study has been supervised and approved by the ethics committee of the First Affiliated Hospital of Nanjing Medical University (Jiangsu Province Hospital).

Why do we carry out this study? At present, the main surgical management for gastric tumors includes traditional open surgery and laparoscopic surgery. In recent years, clinical studies have found that laparoscopic gastrectomy can promote the postoperative recovery process of patients, but the potential impact of laparoscopic surgery on the physiology of patients must be paid attention to by anesthesiologists. The aim of this study is to observe the changes of intestinal barrier function, intestinal microecology and postoperative recovery of intestinal function in patients with different depth of neuromuscular blockade (NMB) during laparoscopic gastrectomy.

If you participate in the study, what do you need to do? Inclusion criteria: (1)40-80 years old; (2) Body mass index < 30kg/m2; (3) ASA classification I-Ⅲ; (4) undergoing elective laparoscopic gastrectomy. General anesthesia and the non-depolarizing muscle relaxant rocuronium were given for tracheal intubation and muscle relaxant maintenance. If selected, there is a 50% chance that you will receive a moderate or deep NMB with the non-depolarizing muscle relaxant rocuronium during the operation. We will collect 5 ml venous blood samples and fecal samples before and after the operation. During the operation, 2cm jejunum tissue will be collected. On the first and second day after the operation, 5ml venous blood samples and the first postoperative feces will be collected. We will follow you up within 2 weeks after the operation to record the time of your first exhaust, defecation, feeding and water intake. All the examinations mentioned above, including the detection of intestinal barrier and intestinal microecology through tissue samples, blood and feces, is a research examination (that is, if you do not participate in this study, you do not need to accept this examination), which will not harm your body.

Who should not participate in the study? Exclusion criteria: (1) Preoperative history

of inflammatory intestinal diseases, intestinal flora disorders, obstructive jaundice, intestinal obstruction, irritable bowel syndrome and other digestive diseases; (2) Severe heart, lung, liver, kidney, brain and other diseases; (3) Serious infection, pancreatitis, burns, trauma, need a large dose, long-term use of antibiotics before the operation; (4) A history of abdominal surgery; (5) Combined with gravis myasthenia, serious electrolyte disorders or neuromuscular diseases. If you have any situation mentioned above, you will not be included in this study.

What are the risks of participating in a study? All anesthetic drugs have the potential to produce side effects, including neuromuscular relaxation drugs which can cause allergies, injection pain, etc. Since the drugs used in this study, such as rocuronium, are common anesthetics in clinical anesthesia, these side effects may occur as long as you accept this treatment, even if you do not participate in this clinical study.

What are the benefits of participating in the study? Your condition may be improved if you participate this study. And it may help determine which treatment is a safer and more effective management for other patients with similar conditions.

Do I have to pay for the study? In order to compensate you for any inconvenience that may be caused by your participation in this study. The study will cover the cost of tissue, blood and stool tests and registration fees during follow-up. However, the anesthesia-related drugs are not free. We will strengthen the examination to observe the possible side effects and adverse events caused by muscle relaxants, such as allergy and respiratory depression, and take measures to prevent and cure them. However, if there are any advert events, the cost of other treatments will not be covered. If there is any harm related to the test, the treatment and compensation will be provided according to the relevant provisions of the state.

Is personal information confidential? Your medical records will be kept in the hospital, and researchers, research authorities, and ethics committees will be allowed access to your medical records. Any public report of the results of this study will not disclose your personal identity. To the extent permitted by law, we will make every effort to protect the privacy of your personal medical data.

Do I have to take part in the study? Participation in the study is completely voluntary. You may refuse to participate in the study or withdraw from the study at any time during the study, which will not affect your doctor's treatment. If you do not participate in the study or you drop out of the study, there are many alternative drugs, such as cis-atracurium, neostigmine, etc. If you decide to withdraw from this study, please contact

your doctor. You may be required to have an examination that will protect your health.

***Subject statement*:** I have read the description of this study above and fully understand the risks and benefits of participating in this study. I volunteered for this study.

I agree □ ***or reject*** □ the use of my medical records and pathological specimens for other studies other than this study.

Participant's signature: date: _ _ _ _ _ year _ _ _ _ day _ _ _ _ _

Participant's contact number:

Doctor statement: I confirm that I have explained to the patient the details of this study, in particular the risks and benefits associated with participating in this study.

Doctor's signature: date: _ _ _ _ _ _ year _ _ _ _ day _ _ _ _ _

Doctor's work phone:

Ethics committee of the First Affiliated Hospital of Nanjing Medical University (Jiangsu Province Hospital). **Ethics committee tel:** 025-68306360