Project Name: Effect of general anesthesia with benzzolam-induced laryngeal mask on the quality of recovery after day surgery in elderly patients: a comparative study with etomidate induction

Version number: V 2.0

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Informed consent form and informed information page

Dear patient / legal agent:

We (we invite your family) to participate in a study on the effect of general anesthesia on the quality of recovery after day surgery in elderly patients: a Comparative Study with etomidate induction. Cases included in the study will be treated as medical routine in the department. The information and data collected in this study are all routine clinical information and data, without any additional treatment or examination test items, and with no additional patient risk and treatment costs. Before you decide whether to participate in the study, please read the following as carefully as possible, which can help you: 1. Understand the background of the study and the purpose and significance of the study; 2. Know the procedures and duration of the study; 3. Clarify the possible benefits, discomfort and risks that may bring to you after participating in the study. If you wish, you can also discuss it with your relatives, friends, or ask your doctor to help you make a decision on whether to participate in this clinical study. Ask any questions to the doctor in charge of the study.

I. Research background and purpose

Elderly patients have reduced organ function, often with comorbidities, and the incidence of complications and mortality after undergoing anesthesia and surgical trauma are significantly higher than other adult patients.

Remazolam (RT) is a new ultra-short-acting benzodiazepine drug that has been approved for clinical use since 2019. Remazolam acts on the γ -aminobutyric acid (GABA) receptor, which can be rapidly

hydrolyzed into an inactive carboxylate metabolite by ubiquitous tissue esterases. Compared to the classic benzodiazepine midazolam, it starts earlier and recovers faster. Also, like the other benzodiazepines, remazolam can be antagonized by a flumazenide injection. These advantages of remazolam have greatly attracted the attention of anesthesiologists as well as anesthesia practitioners, but there is still no answer on the quality of recovery of remazolam application in elderly patients and day surgery. In this study, we aimed to evaluate the quality of recovery after general anesthesia in elderly patients with induced day surgery to better balance postoperative recovery quality with safety and compare the recovery quality after Remazolam and etomidate-induced general anesthesia, so as to better guide the choice of intraoperative induced medication in elderly patients. The results were used in anesthesia induction drug selection to improve the quality of postoperative recovery.

II. Study design, methods, and procedures

The sponsor of this project is the Department of Anesthesiology and Perioperative Medicine of the First Affiliated Hospital of the Air Force Military Medical University. The Air Force and the Ethics Committee of the First Affiliated Hospital of Medical University considered this study according to the principles of the Declaration of Helsinki and complied with medical treatment

morals. The participating researchers are all clinicians in the department of anesthesiology and day ward, qualified as medical practitioners, with relevant treatment skills including rescue, have received clinical trial research training, and obtained relevant certificates.

This study is a single-center, randomized, double-blind, parallel-controlled clinical trial, expecting 112 eligible patients undergoing

day surgery to voluntarily participate. These patients have certain inclusion criteria, including specifically:

(1) Age:> 65 years old and above;

(2) The American Association of Anesthesiologists (ASA) is grades I-III;

(3) The body mass index (body mass index) was 18-30 kg/m^2;

(4) Voluntary provide written informed consent;

(5) The patient underwent day surgery under general anesthesia with a laryngeal mask;

Excluding patients with the following events, the exclusion criteria, specifically:

(1) Cognitive dysfunction, and neuropsychiatric disorders

(2) Use of benzodiazepines or opioids within 1 month

(3) Patients with contraindications or allergies to benzodiazepines, opioids, etomidates and their components

(4) Patients estimated to have a difficult airway

(5) Have adrenocortical insufficiency, porphyria, or receiving chronic corticosteroids

This study patients randomly divided into two groups, namely remazolam group and etomidate group, if you are eligible for inclusion and willing to participate in the study, will be randomized to remazolam group and etomidate group, two groups of anesthesia maintenance regimen consistent, only in the induction of anesthesia, remazolam group for remazolam induced anesthesia, and etomidate group for etomidate induced anesthesia. Your inclusion in the different groups will not affect the usual treatment of your doctor.

This study will record your personal situation and information related to the disease, from the operation before you participate in the trial, will record preoperative, intraoperative and postoperative, including age, gender, medical history, general medical examination (such as blood pressure, heart rate), drug use (e. g., drug dosage), and follow-up to 2 days after surgery, to collect prognosis information such as postoperative recovery quality. The above routine treatment measures and medical examination items are all necessary clinical routine items in the perioperative treatment process of surgical patients. This study has no special examination and treatment programs, and no additional burden on patients.

III. Benefits of participating in this study

You will not directly benefit from your participation in this project. The clinical results obtained by you and other subjects participating in this study may contribute to the optimization of the postoperative analgesia regimen for patients undergoing day surgery similar to you.

Ⅳ. Possible risks of participating in this study

Remmazolam, used in this study, is a novel benzodiazepine, a central nervous system inhibitor with sedative-hypnotic effects. The possible risk is the risk of routine postoperative sedation, such as possible excessive sedation, but also mild respiratory depression.

The etomidate used in this study is a hypnotic intravenous general anesthetic, which is one of the drugs commonly used in anesthesia induction. Possible risks are the transient postoperative inhibition of adrenocortical function and myoclonus.

The physician will do everything he can to prevent and treat possible damage due to this study drug (Remimazolam and etomidate) (e. g.

administer a mask for oxygen when respiratory depression occurs). If the damage related to the study drug (Remimazolam and etomidate) occurs in the clinical study, the medical expert committee will identify whether it is related to the intervention, and will provide compensation in accordance with the Good Clinical Practice of China. This study has prepared reasonable preservation measures for you (such as anesthesia machine, ECG monitoring, rescue drugs, etc.) that will protect your legitimate rights and interests as much as possible.

Ⅴ. The costs associated with participation in this trial

Whether or whether you participate in this study, the relevant diagnosis and treatment measures will be conducted in accordance with the medical routine. The drugs used in the study are commonly used in clinical practice with no additional cost, and the treatment costs (except remazolam and etomidate) are borne by the patient. Remimazolam and etomidate used in the study were provided free of charge by Yichang Renfu Pharmaceutical Co., Ltd.

Ⅵ. Confidentiality

After the study, we will organize and analyze the collected information and data. Finally, the results and conclusions will be compiled and submitted and published. In the various medical data records of this study, your name will be replaced by the pinyin abbreviation. Your medical records and information will be kept in the hospital, and may be approved by the investigator, the research authority and the ethics committee. Any public report on the results of this study will not disclose your personal identity.

Ⅶ. Your rights

You / your family member participation in the study is completely voluntary, you / your loved one can withdraw from the study at any time without any reason, which will not affect the relationship between your family member and medical staff and any future medical

treatment and rights and interests; all personal data and observation records of you / your loved one are confidential and only for the purpose of the study; you may keep abreast about the relevant information during the study or refer to the bed doctor. If there is still any doubt or an emergency, please contact the project leader at 029-84775343.

Ⅷ. Contact information of the ethics Committee

The trial protocol was approved by the hospital ethics committee and had any violation of the study protocol during the trial

Situation, you can complain directly to the hospital ethics committee. Tel.: 029-84771794, email:

xjy yllwyh @163.com 。

Subject informed consent signature page

I have read the above informed consent form in detail and understood the purpose of the study and the possible benefits and risks of participating in it. The above medical terms have been clearly explained by the investigator. I had the opportunity to ask questions and all the questions were answered easily. I may choose not to participate in this study, or to withdraw at any time after notifying the responsible doctor, and any of my medical treatment and interests will not be affected accordingly. If I need other treatment, or if I do not adhere to the study plan, or if a study-related injury occurs, or for any other reason, the responsible doctor may terminate my continued participation in this study.

I have read the above informed consent form and obtained a copy, and my physician gave me a detailed explanation. I volunteered for this clinical trial. I agree with the relevant parties to check the data collected from the trial study against my original medical records.

Subject block name: _____ Subject Tel: _____

Subject Signature: _____

Date:_____ Year _____ month _____ day

(Note: if the subject has no civil capacity, the guardian shall sign; if the subject has limited civil capacity, the subject and his guardian need capacity)

Name of the guardian in block letter: _____ Relationship to the subject:_____ Guardian Tel:_____

Signature of guardian:_____

date:_____ Year _____ month _____ day

Fair Witness signature (if applicable): _____

Date:_____ Year _____ month _____ day

(If the subject or his guardian is not able to read, an impartial witness is required to sign, the impartial witness to read the informed consent and other written materials, and witness the informed consent.)

I confirm that I have explained to the patient the details of the contents of this clinical trial, including the possible benefits and risks of the patient, and answered all the questions raised by the patient.

Investigator Signature (block letters):_____

date:_____ Year _____ month _____ day

Investigator Tel.:_____

date:_____ Year _____ month _____ day