The effectiveness and safety of propofol combined with different doses of esketamine anesthesia during loop electrosurgical excision

January 1,2022

Informed Consent Form

Research Background:

Deer patients:

You will be invited to participate in a study hosted by the Department of Anesthesiology, the First Affiliated Hospital of Chongqing Medical University. This is a clinical study to compare the application of different doses of esketamine combined with propofol in loop electrosurgical excision procedure (LEEP). You are invited to participate in this study because you plan to undergo LEEP in our hospital.

This informed consent form provides you with information to help you decide whether to participate in this clinical study. Your participation in this study is voluntary. Ethical approval was obtained from the Ethics Committee. If you agree to participate in the study, please read the following instructions:

Please read it carefully. If you have any questions, please refer them to the person in charge of the study.

Objectives of the study:

Loop electrosurgical excision procedure (LEEP) is an effective and widely used surgical treatment for cervical lesions like: cervical intraepithelial neoplasi a (CIN),cervical erosion, cervicitis and so on. The loop electrosurgical generate s high frequency electric waves, When contacts with the tissue, it absorbs the high frequency electric waves and instantly generates high heat to achieve the purpose of tissue resection. Despite LEEP being a simple procedure, it causes significant pain and discomfort. It was reported that the mean VAS score durin g LEEP was as high as 4, even in the presence of local anesthesia. Physical movement during the surgery severely impacts the surgeon’s ability to perform the procedure accurately. Therefore, an effective anesthesia protocal is critical.

Propofol is common intravenous anesthetic for LEEP, with sedative and amnestic properties as well as a rapid onset of action and recovery. However, propofol does not have analgesic effects, and it increases the risks of hemodynamic and respiratory depression in a dose-dependent manner. Esketamine (ESK), as a derivative of phencyclidine is an enantiomer of ketamine, with similar sedative and analgesic effects, faster clearance, and lower incidence of toxicity compared with ketamine.

This study aims to evaluate the anesthetic effect and safety of propofol combined with different doses of ESK in LEEP.

Research process and Methods:

Ninety patients will participate in this study, and after preliminary screening, you meet the criteria for inclusion in the study. The specific research process is as follows:

If you agree to participate in the study, you will be assigned to one of three computer-generated random numbers and a medical record will be created. Participants will be unaware of their group assignment.

We will regularly collect your heart rate, blood pressure, respiration and other vital signs, all of which were non-invasive procedures. In addition, We will collect 1 ml of venous blood from your arms, which will be taken by a professional for you ,a total of 2 times. When you wake up after surgery, we will ask you about nausea, vomiting, dizziness, and pain.

Possible benefits of the study:

This study aims to evaluate the effect of propofol combined with esketamine on the circulation and respiratory system, complications and postoperative recovery in LEEP surgery, and to guide the choice of anesthetic drugs for LEEP, in order to make the operation safer, faster recovery and higher comfort for patients.

Research Risks and discomfort:

The intervention of this study does not involve any additional invasive procedures except for two blood draws, and is performed after anesthesia, which will not cause harm to your body, mind, social life, or in any other way. If there is any discomfort during the study, we will intervene in time, and our hospital has the corresponding operation process and treatment measures to ensure your safety.

Your sample collection will be strictly aseptic and there may be small risks associated with sample collection, such as transient local cyanosis from blood drawing, mild dizziness in a few people, or extremely rare needle infection.

Other therapeutic interventions: There were no other interventions in this study.

Privacy issues: (Privacy protection in the process and privacy protection in the publication of results)

If you decide to participate in this study, your personal data will be kept confidential. Your blood specimen will be identified by the study number, not by your name. Information that could identify you will not be disclosed to members outside the research group unless your permission. The data of this study will be sealed after writing of the paper. All study members and study sponsors are required to keep your identity confidential. Your files will be kept in the Anesthesiology Department filing cabinet of the First Affiliated Hospital of Chongqing Medical University for researchers only. In order to ensure that the study is carried out in accordance with the regulations, the government authorities or members of the ethical committee can access your personal data at the research institution if necessary. If the results of this research are published, no identifying information will be associated with you.

Costs and Compensation:

The costs of your anesthesia will not increase in this study. If you are harmed as a result of participating in this study, you will receive free treatment or compensation for any injury related to this clinical study. The treatment costs were provided by our research group.

Freedom to withdraw:

As a participant, you have the right to know the information and progress of the study at any time, and you have the right to decide voluntarily whether to continue or not to continue participating in the study. After participating, whether there is any harm, whether it is serious or not, you can choose to notify the researcher at any time without any reason to request to withdraw from the study, and your data will not be included in the research results, and your medical treatment and rights will not be affected in any way. If you continue to participate in the study and it causes serious harm to you, the researcher will also terminate the study.

However, during the study period, please provide the researcher with the truth about your medical history and current physical condition, tell the research doctor any discomfort you may experience during the study, tell the researchers whether you have

participated in any other studies in the past or are currently participating in other studies. If you do not follow the study plan, or if you suffer any injury related to the study or for any other reason, the researchers can terminate your participation in this study.

Contact information:

If you have any questions related to this study, or have any discomfort or injury during the study, or if you have any questions about the rights of participants in this study, you may contact Dr. Qian Wu at __18716636311_.

Post-trial benefit sharing:

After the study is completed, the corresponding results will be published in domestic and foreign journals. You can learn about the research findings through the researcher.

Signature of informed consent:

I have read this informed consent form, and my doctor _____has given me a detailed explanation of the purpose, content, risks, and benefits of the trial, and has answered all my questions. I am aware of the study, and I voluntarily participate in the study.

Signature of subject:_____

Date: _____

Signature of investigator:_____

Date: _____