Participant's Informed Consent

Protocol name: The influence of low-dose ESketamine on postoperative depressive symptoms in breast cancer patients (EASE): study protocol for a randomised controlled trial

Program version number version date: 03, March 17, 2023
Informed Consent Version Number Version Date: 01, March 17, 2023
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You are being invited to participate in a clinical research study. This information sheet gives you information to help you decide whether or not to participate in this clinical research study. This information sheet gives you information to help you decide whether or not to participate in this clinical study. Please read it carefully and if you have any questions, please ask the investigator in charge of the study.

Your participation in this study is voluntary. This study has been reviewed by the Ethics Review Board of this research institution.

Research Aim: Escitalopram is a commonly used intravenous anesthetic drug, which has been approved for the treatment of clinically refractory depression and major depressive disorder. Studies have shown that esketamine has a rapid onset of action, can rapidly eliminate suicidal intent in patients, and low-dose maintenance therapy can help stabilize patients' conditions with fewer adverse effects, making it a hot topic in current research on antidepressant medications. Studies have shown that brain-derived neurotrophic factors and alterations in resting brain functional connectivity may respond to the efficacy of antidepressant treatment. The purpose of this study is to investigate the effect of prophylactic administration of esketamine on postoperative depression in breast cancer patients and its effect on brain-derived neurotrophic factor and resting state brain functional connectivity.

Study Process: If you agree to participate in this study, we will number you and
create a medical record file. During the study we will need to collect some of your specimens, MRI information, etc., which will be sampled and collected for you by a professional.

Blood Collection: 3 mL of venous blood will be drawn from your arm, once before surgery and once early in the morning of Day 1, for a total of 2 samples. Your sample will only be used in this study to measure the level of brain-derived neurotrophic factor.

Magnetic Resonance Data Collection: You will be taken to the MRI room by the investigator for a 10-minute procedure, once before and once on Day 1, for a total of 2 times. Your data will only be used to analyze the functional status of the brain for this study.

Scale Assessment: We will ask you about your pain and depression status before surgery, at 3 day postoperative, at 5 day postoperative or at discharge, at 4 week postoperative, and at 12 week postoperative, either face-to-face or by phone contact.

Risks and Discomfort: All information will be confidential to you. Your specimen collection will be performed in strict accordance with strict aseptic requirements. There may be some very minor risks associated with specimen collection, including transient pain, localized bruising, and in a few cases mild dizziness, or very rare needle infections.

Benefit: The use of a commonly used intravenous general anesthetic drug in this study may be beneficial in improving your mood after surgery as well as reducing the occurrence of adverse times such as your level of postoperative pain. Therefore, you may potentially benefit by participating in this study.

Costs: Propofol, sufentanil, remifentanil, ropivacaine, and esketamine are drugs that are already available in China and are routinely used for anesthesia, so you will be responsible for the cost of the study medications and related treatment. The study medications and associated costs will be your responsibility, and routine treatments and investigations for other co-morbidities will not be covered. Resting-state MRI and blood tests for brain-derived neurotrophic factors will be free of charge.

Compensation: There is no additional compensation to you for this study.
As a research participant, you have the following responsibilities: to be truthful about your medical history and current physical condition; to tell the study doctor about any discomfort you experience during this study; and to tell the study doctor if you have recently participated in other research studies or are currently participating in other research studies.

Privacy Issues: If you decide to participate in this study, your participation in the study and your personal information during the study will be kept confidential. Your biospecimen will be identified by the study number and not by your name. Information that identifies you will not be shared with anyone outside of the research team unless you give your permission. All study members and the study sponsor are asked to keep your identity confidential. Your file will be kept in a locked filing cabinet and will be accessible only to researchers. If necessary to ensure that the study is conducted in accordance with the regulations, members of the government regulatory or ethical review committee will be given access to your personal data at the research unit as required. No personal information about you will be disclosed when the results of this study are published.

If you are harmed as a result of participating in this study: You may be entitled to free treatment and/or compensation for damages related to this clinical study.

You may choose not to participate in this study, or you may request to withdraw from the study at any time by notifying the investigator that your data will not be included in the results of the study, and any of your medical treatment and rights will not be affected as a result.

Disposal of Biological Specimens and Information at the End of the Study: The investigator will retain essential documents related to the clinical trial for 5 years after completion of the study. Blood specimens will be disposed of in accordance with the Medical Waste Management Regulations.

The research physician may terminate your continued participation in this study if you need other treatment, or if you do not follow the study plan, or if a study-related injury occurs or for any other reason.

You will be kept informed of the information and progress of the study, and we
will notify you of any new safety information related to the study. If you have questions about this study, or if you experience any discomfort or injury during the study, or if you have questions about the rights and interests of participants in this study, you may contact Xuesheng Liu at 0551-62922304.

If you have any questions or claims regarding your rights and health from participating in this study, you may contact the Institutional Ethics Committee at 62923537; Contact: Tao Zhou
Informed consent 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 can choose not to participate in the study or withdraw at any time by notifying the researcher without discrimination or retaliation, and any of my medical treatment and rights will not be affected as a result.

The study physician may terminate my continued participation in this study if I need other treatment, or if I do not comply with the study plan, or if a study-related injury occurs or for any other reason.

I will receive a signed copy of the Informed Consent Form.

Subject's Name: __________________________
Subject's signature: _________________________
Date: __________________________

I have accurately communicated this document to the subject, requesting that he/she has carefully read this informed consent form and that any questions or issues raised are carefully answered.

Researcher's Name: _________________________
Researcher's signature: _______________________
Date: __________________________