Supplementary file 2

INFORMED CONSENT

CHoice of Anaesthesia in Microelectrode Recording-guided DeeP-brain StImulation for ParkinsON's Disease (CHAMPION)

Project entrust organization: Beijing Tiantan Hospital, CMU

Contract Research Organization: N/A

Version：2.3

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INFORMATION SHEET

You have been diagnosed with **Parkinson's disease,** and you will receive elective bilateral subthalamic nucleus-deep brain stimulation.

We would like to invite you to participate in our study, which is **"Choice of Anaesthesia in Microelectrode Recording-guided Deep-brain Stimulation for Parkinson's Disease**", to observe the effect of general anaesthesia and conscious sedation on microelectrode recording and clinical outcome. This study was approved by the Ethics Committee of Beijing Tiantan Hospital of Capital Medical University. During our study, we will follow the Declaration of Helsinki.

Before you decide whether to participate in this clinical trial, please take time to review this information carefully. This form describes the purpose, procedure, study duration, risks and possible benefits of participating in the study. You may also wish to talk to others, including your friends, family, or discuss with your anesthesiologist, about your participation in this study.

1. PURPOSE OF THIS STUDY

Deep brain stimulation (DBS) implantation under general anaesthesia has been applied to Parkinson's disease patients with disabling off-medication symptoms or medical comorbidities. However, general anaesthetics may affect intraoperative microelectrode recording to varying degrees. At present, there are few studies on the effects of sedative or general anaesthetics on multiunit activity characteristics performed by microelectrode recording in Parkinson's disease patients during DBS. Therefore, the effect of the choice of anaesthesia on microelectrode recording remained unclear in this population. Additionally, there is a lack of high-quality clinical data to confirm the feasibility of general anaesthesia for microelectrode recording during subthalamic nucleus-DBS. We designed this randomized controlled study to compare microelectrode recording mapping and clinical efficacy after surgery in Parkinson's disease patients with general anesthesia or conscious sedation to explore alternative anesthesia methods for DBS patients.

2. NUMBER of PARTICIPANTS

In total, 188 patients will be included in the study.

3. DURATION OF THIS STUDY

This study will last 2 years, and we will collect postoperative information until 6 months postoperatively.

4. PROCESS OF THIS STUDY

If you are willing to participate in the study, please sign this informed consent form, and you will be examined including the following:

- Physical examination and medical history inquiry
- Vital signs: respiratory, body temperature, heart rate and blood pressure.
- Severity of Parkinson's disease symptoms: the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS)-III and Hoehn and Yahr Scale.

- Blood test
- Electrocardiography

If you met the inclusion and exclusion criteria, the neurosurgeon and anesthesiologist evaluated your safety, and with the agreement of both of them, you could be allocated into two groups randomly. With the computer-generated table, you will be randomly allocated to receive one of anesthesia management in an equal chance. We will implement your anesthesia according to your group. During the whole study, we will collect your response to different anesthesia methods and your health status through close intraoperative monitoring and a series of examinations at 2 h, 24 h, 2 days and 3 days after you receive treatment. We will notify you to conduct face-to-face follow-up at the functional neurosurgery clinic 6 months after the end of treatment to assess the clinical efficacy, cognitive function, quality of life, adverse events and satisfaction. This study will compare MER mapping information and clinical efficacy to determine which anesthesia treatment is better for Parkinson's disease patients and finally to optimize the treatment of patients.

5. THE DIFFERENCE OF TWO ANESTEHSIA MANAGEMENT

The type of anaesthesia is an important factor not only for the accuracy of microelectrode recording but also for the safety of the operation. At present, the optimal anaesthesia choice and management for Parkinson's disease patients during DBS include local anaesthesia, conscious sedation and general anaesthesia. Conscious sedation is preferred, and asleep-awake-asleep using dexmedetomidine (DEX) is the commonly used anaesthesia method among clinical centres for its obvious benefits: allowing the surgeon to analyse the spike characteristics of microelectrode recording and evaluate the clinical benefits and side effects through intraoperative clinical tests. However, it may not be applicable to some special patients (unable to keep supine position during the operation, dyspnoea, severe pain, physical deformity, severe anxiety, fear and severe circulatory diseases, etc.). Additionally, it is too serious to cooperate with surgeons when awake for patients disabling off-medication symptoms or medical comorbidities. There is also an increased risk of accidental intracerebral haemorrhage during surgery due to coughing or tremor. Therefore, it is still necessary to perform microelectrode recording tests under general anesthesia.

Many studies on DBS implantation under general anaesthesia have been conducted in recent years, but the clinical results of these studies vary. Some researchers considered that postoperative symptom improvement was better in the local anaesthesia groups, although some researchers suggested that symptom improvement is similar between general anaesthesia and local anaesthesia surgery. Abandoning awake clinical testing does not lead to less motor improvement. At present, there is a lack of high-quality clinical data to confirm the feasibility of general anaesthesia for microelectrode recording. The purpose of this study was to compare microelectrode recording mapping in Parkinson's disease patients with general anaesthesia or conscious sedation during the subthalamic nucleus (DBS) to explore alternative anaesthesia methods for DBS patients.

6. OTHER TREATMENT CHOICE

In clinical practice, anesthesia management for Parkinson's disease patients includes general anesthesia and conscious sedation. If you do not participate in this study, your intraoperative anesthetic scheme is mainly arranged and formulated by the anesthesiologist according to clinical experience.

7. WHO CAN BE SELECTED for the study?

1) Age ranges from 50 to 80 years old,
2) American Society of Anesthesiologists (ASA) physical status II to III,
3) After receiving bilateral STN-DBS,
4) Signing the informed consent.

8. WHO SHOULD NOT PARTICIPATE in the STUDY

If you have the following condition, you should not participate in the study:

1) Suffering from obstructive sleep apnea,
2) Body mass index (BMI) > 30 kg/m^2,
3) Suspected difficult airway condition,
4) Suspected to be uncooperative during surgery (i.e., severe tension and anxiety),
5) Severe organ dysfunction (i.e., heart failure, renal or liver dysfunction),
6) Known allergy to the anaesthetics.

9. POSSIBLE BENEFITS of PARTICIPATING in theSTUDY

Your prognosis may or may not improve as a result of participating in this study, and the information from this study will help determine which anesthesia management can be safer and more effective applied to other patients with similar conditions.

10. POSSIBLE ADVERSE REACTIONS, RISKS and DISCOMFORT, INCONVENIENCES of PARTICIPATING in the STUDY

The monitoring methods, anesthesia methods, anesthetic drugs and anesthesia maintenance used in this study are all routine clinical practice, and there will be no additional risks related to the study. It is possible that related discomfort or adverse events will happen during your anesthesia and operation, including respiratory depression, circulation depression, arrest, cardiac arythm, myocardial infarction, pulmonary embolism, drug adverse reactions and cerebrovascular complications (hemorrhage and infarction). If you experience adverse reactions or discomfort due to surgical procedures and anesthesia, the researchers will make corrections promptly.

During the study, you need to undergo doctor inquiry and questionnaire, which may cause inconvenience to you.

11. CONFIDENTIALITY OF PERSONAL INFORMATION

Your medical records (study records/CRF, lab sheets, etc.) will be kept intact at the hospital. Your doctor will record the results of tests and other tests on your medical record. Researchers, ethics committees, and drug regulators will be allowed access to your medical records. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the law.

12. HOW TO GET MORE INFORMATION?

You can ask any questions about this study at any time and get answers. Your anesthesiologist will be ready to answer any of your questions before, during and after the study.

13. RELATED EXPENSES

You need to pay for routine anesthetic drugs, equipment, operation, monitoring and examination. Our assessment of Parkinson's disease severity, cognitive function, quality of life, clinical efficacy, etc., through the scale is free of charge, and your participation in this study will not increase your additional costs. If any medical expense occurs due to an adverse event, you will be exempted from the charge.

14. YOU MAY VOLUNTARILY CHOOSE TO PARTICIPATE in STUDY and WITHDRAW from STUDY

Whether to participate in the study is entirely up to you. You may refuse to participate in the study or withdraw from the study at any time during the study, which will not affect your relationship with your doctor or affect your medical service or other benefits.

Before making a decision, you can discuss with your family or friend, or you can talk with your doctor for any question, until you fully understand this study.

15. HOW THE STUDY MAY EFFECT YOUR LIFE?

You may feel the visit and examination uncomfortable, and special arrangement is needed. You can consult your doctor in any steps of the study.

In addition, signing this informed consent means that you agree not to participate in any other clinical research related to drugs or medical devices during the whole study period.

16. CONSULTING

If you have any related questions, please contact Dr. Xie Sining (phone: 010-59976656 or cell phone: 13581874076).

If you have any concerns about your personal benefit, or you want to complain or express your concerns about the study, please contact the Ethics Committee of Beijing Tiantan Hospital of Capital Medical University (phone: 010-59978555 or e-mail: ttyyirb@163.com).

SIGNATURE PAGE of AGREEMENT

Study tile: CHoice of Anaesthesia in Microelectrode Recording-guided DeeP-brain StImulation for Parkinson's Disease

Principal investigator: Ruquan Han, Beijing Tiantan Hospital, CMU

DECLARATION of CONSENT

I have read the introduction about the study above and have the opportunity to discuss with doctors and ask the questions about the study. All my questions have been answered satisfactorily.

I am aware of the possible risks and benefits of participating in this study. I know that participating in the study is voluntary. I have taken it into full consideration and know that:

· I can ask my doctor for more information at any time.

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

I am also aware that if I withdraw from the study, especially if I withdraw due to medication, it will be of great benefit to the whole study if I tell my doctor about my condition and complete the corresponding physical examination and physical and chemical inspection.

If I need to take any other medication due to a change in my condition, I will consult my doctor beforehand or tell him afterwards truthfully.

I agree that the ethics committee of the drug regulatory authority or the representative of the sponsor may have access to my research information.

I will be provided with a signed and dated copy of the informed consent.

Ultimately, I agreed to participate in the study and promised to follow my doctors' advice as much as possible.

Signiture of patient/legal relative:

Relation:

Date: **(yyy/mm/dd)**

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

Aignature of doctor:

Date: **(yyy/mm/dd)**