Informed Consent Form

Study on the Characteristics of Non-targeted Metabolomics and EEG of Postoperative Cognitive Dysfunction in Elderly Patients

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Introduction

We sincerely invite you to participate in this research entitled "Study on the Characteristics of Non-targeted Metabolomics and EEG of Postoperative Cognitive Dysfunction in Elderly Patients". Before you agree to participate in this study, it is necessary to understand the purpose and content of this study. Please read this form carefully and discuss it with your doctor, family and friends. If there is anything unclear or you want to know more, please consult your doctor or contact the researcher directly.

What is the purpose of our study?

Postoperative cognitive dysfunction (POCD) refers to the difficulties of orientation, cognition, communication, memory and abstract thinking of patients after anesthesia and surgery. And/or accompanied by the decline of the ability in social activities, such as the change of personality, social ability of language and behavior, cognitive function and life skills. POCD is a common complication of central nervous system in elderly patients after operation, with an early incidence of about 21% and a long-term incidence of about 35%. According to the current research on Alzheimer's disease (AD) and POCD in the elderly, it has been found that they have similar pathological basis and some homologous related genes. Altogether, POCD is closely related to molecular pathway neuropsychiatric diseases (such as dementia, depression and Alzheimer's disease). Researchers have come up with various hypotheses to reveal the underlying mechanisms of

POCD, including neuritis, oxidative stress, autophagy disorder, synaptic dysfunction, and lack of neurotrophic support. To date, apart from evaluating with scales, CT Scan and EEG analysis, there is neither exact biomarkers for monitoring and diagnosing POCD, nor clear relationships between specific EEG changes and diagnosis of POCD, so that the diagnosis of early POCD only stays in the evaluation of clinical symptoms and scales. Therefore, our study aims to provide an effective basis for early diagnosis and treatment of clinical POCD through multivariate analyses of clinical scales combined with EEG analysis of patients.

How is the research conducted?

This study does not involve intervention on subjects and does not increase the risk of them. The subjects are elderly patients undergoing elective non-craniocerebral operations under general anesthesia. The preoperative health status, emotion and cognitive function are detected, and the patients with early clinical POCD are screened out by comparing with the scores of postoperative cognitive function scales. The abnormal EEG waveform of POCD patients is found by EEG monitoring. We aim to provide therapeutic support for the prevention and treatment of POCD through the screening of POCD in elderly patients, statistical analysis of related factors and multivariate analysis.

Inclusion/ Exclusion criteria:

Inclusion criteria:

(1) Elderly patients with ASA I-II who are 60 yr or older and have not undergone craniocerebral operations.

(2) Ability to listen, speak, understand and cooperate with neuropsychological tests, and Chinese is the mother language.

(3) Patients sign the informed consent form.

(4) Follow-up is possible.

(5) The liver and kidney function, cardiopulmonary function are normal or compensatory.

Exclusion criteria:

(1) Patients who have been diagnosed with AD.

(2) Patients who can't cooperate with the evaluation of the cognitive scales preoperatively and the corresponding scores are abnormal.

(3) Being taking antidepressants or sedatives, and being dependent on drugs or alcohol.

(4) Patients who plan to undergo carotid artery, intracranial and cardiac surgery

(5) Have undergone one or more operations within six months.

(6) Have had participated in other clinical researches within six months.

Data and indicators to be collected:

(1) Basic information of patients relevant to the study:

Name, age, sex, height and weight

(2) Physical examination: general condition, skin, head and neck, lymph

nodes, thyroid, musculoskeletal/limb, cardiovascular, lung, chest and abdomen

(3) General clinical data: combined diseases and drugs, etc.

Outcomes:

Primary outcome:

1. The patients' preoperative basic information such as height, weight, vital signs, data of laboratory examinations and preoperative health status.

2. Intraoperative anesthesia methods, medication, vital signs, circulation volume, operation time, blood loss and EEG data.

3. Postoperative evaluation of cognitive function scales and delirium scale (3D-CAM), EEG data.

What is the possibility of suspending the test?

Patients or family members voluntarily request to quit

How many people participate in this study?

This study is expected to recruit 200 elderly patients who are 60 yr or older undergoing non-craniocerebral operation.

Is the research dangerous?

This study is an observational study and will not interfere with your treatment plan. There is no danger.

If you don't want to participate in this research, are there any other alternatives?

If you decide not to participate in this study, your researcher will absolutely

respect your choice.

Benefits

To provide theoretical basis for early detection, diagnosis and treatment of POCD.

Do you need to pay extra medical expenses?

This clinical trial does not require patients to pay any additional medical expenses.

Compensation

This study is an observational study, which neither requires patients to buy medical articles or drugs, nor involves medical reimbursement of injury events resulted from the study, so it doesn't involve compensation.

Is my information confidential?

During the research, all of your information is strictly confidential. Only the relevant personnel can view your medical records, so that they can check the accuracy of the collected information and ensure the normal research. Any electronically transmitted information will be renamed to guarantee the confidentiality of the information, which will be protected by passwords in all computers. The results of this study may be reported at medical conferences and published in scientific journals. However, any identifiable personal information of you will not be used.

Rights of subjects

You have the right to decide whether to participate in the research, which

is completely voluntary, without compulsion. If you can't make a decision immediately, you have plenty of time to discuss with your relatives and friends before that. If you decide not to participate in this study, your regular treatment or the relationships with medical staff will not be affected. If you decide to take part in it, no special circumstances, we hope you can complete the experiment. Of course, you have the right to quit at any time without any reason.

During the test, you can keep abreast of the research-related information, and you will be informed in time if you get any news that may affect the subject's continued participation in the trial.

Subject's responsibilities

As a subject, you have the following responsibilities: provide relevant medical history and current physical condition; Inform the doctor of any discomfort during the study; Tell researchers whether you have participated in or are participating in other studies recently.

Who will perform this experiment?

This study will be carried out by the Department of Anesthesiology, Shanghai Ninth People's Hospital，Shanghai Jiao Tong University School of Medicine.

Who should I contact for more information?

After reading the introduction and discussing with your doctor, if you have any other questions or concerns, please contact the following people:

Researcher: Lei Zhang

Telephone number: 18717822662

Address: Department of Anesthesiology, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine.

Who approved the research?

This study has been approved by the Medical Ethics Committee of the Ninth People's Hospital affiliated to Shanghai Jiao Tong University School of Medicine. Anyone who has any questions or complaints about this study can contact the Medical Ethics Committee directly at 021-63057795.

Signature page of informed consent form of subjects

The research doctor has explained to me the purpose, process, possible risks and benefits of this trail. I have read the instructions carefully, and have enough time to ask questions. At present, I have no doubt.

I take part in this experiment voluntarily, and I can quit the experiment at any time for any reason without any loss. I will follow the instructions of the research doctor during the trial. I agree that the data obtained from this experiment can be recorded, stored and processed in a computer. Additionally, I agree that the representatives of the sponsors, members of the ethics committee and representatives of the government management departments can consult my case records under the principle of confidentiality, knowing that the purpose of which is to ensure that the data collected in this study are true, accurate and reliable.

To sum up, I agree to participate in this clinical study, and I have obtained a copy of the signed informed consent form.

Name of the subject：　　Name of Legal Representative：

Signature of the subject：　　Signature of legal representative ：

Relationship between legal representative and subject:

Telephone number of the subject：

Telephone number of legal representative ：

Signature date: _____ Signature date: _____

(Note: If the subject is incapacitated, it will be signed by the guardian)

Name of the researcher: Telephone number of the researcher:

Signature of the researcher: Signature date: _____