Title：The Diversity of Intestinal Microbiota in Patients With Different Sedative-hypnotics and Mechanical Ventilation

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Introduction

You will be invited to participate in a clinical study entitled " The Diversity of Intestinal Microbiota in Patients With Different Sedative-hypnotics." Brain gut axis is a bidirectional regulatory axis of the interaction between central nervous system and digestive system. In view of the existence of brain intestinal axis, there is no relevant report on whether the long-term use of general anesthesia sedatives in children will affect the diversity of intestinal flora. The effects of different general anesthesia sedatives on the diversity of intestinal flora also need to be further studied. Therefore, this subject intends to study the correlation between the most commonly used general anesthesia sedatives, propofol and sevoflurane, and the diversity of intestinal flora under general anesthesia, so as to provide a theoretical basis for the rational use of general anesthesia sedatives in children.

1. Purposes

Bispectral index (BIS) was used to monitor the depth of anesthesia in this study. High throughput sequencing of 16S RNA was used to detect whether the diversity of intestinal flora in children with different sedative-hypnotics was affected or not.

2. No additional medical expenses

The monitoring by BIS detector is free of charge.Invasive arterial blood pressure monitoring is used to ensure the safety of the child. We will take faeces before and after surgery. We will take charge of the detection of the diversity of intestinal flora indicators. There is no additional cost.

3. Possible Risks

The clinical trial does not increase the risk of treatment due to the use of traditional treatment evaluation systems and methods. If you suffer from injury associated to this study, you can receive compensation according to the relevant law and regulation.

4. Benefits

All patients who participate in the study are examined and treated by a clinically experienced doctor. By studying your case, it will help diagnose the disease, provide the necessary advice for your treatment, or provide useful information for the study of the disease. In order to fully protect your rights and interests, we have developed a detailed clinical trial plan, which has been reviewed and approved by the hospital ethics committee, and we will implement clinical trials in strict accordance with the program. Anyone who participates in this experiment will receive a transportation subsidy of 100RMB.

5. Duty of Confidential

For you, all information will be confidential. Information that identifies you will not be disclosed to anyone other than members of the research group so that they can check the accuracy of the information. Your information will be identified by a study

number rather than your name. All the information is encrypted on all computers. No personal information about you will be disclosed.

6. Participation And Withdrawal

Participation in this study is voluntary. You may choose not to participate in this study, or at any time inform to request withdrawal from the study without any reason. Any medical treatment and benefits will not be affected. If you decide to participate in the study, you will be asked to sign an informed consent form. You will receive a signed copy of the informed consent and this introduction.

The study was carried out by the Department of Anesthesiology, Shanghai Ninth People's Hospital.

If you have any questions related to the study after reading the introduction, please contact:
Researcher: Li Jingjie
Phone number: 18019790516
Address: Anesthesiology, Shanghai Ninth People's Hospital

This study has been approved by the Medical Ethics Committee of Shanghai Ninth People's Hospital affiliated to Shanghai Jiaotong University School of Medicine. If you have any questions please contact the ethics committee of Shanghai Ninth People's Hospital at 23271699-5576.

I agree to participate in this clinical trial.
Patient's name:
Signature of Patient/Guardian (Relationship with patient): Date:
Researcher’s name:
Signature of Researcher: Date: