Title：The Neurobehavioral Effects of Anesthetics on Infants With Hearing Impairment

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Introduction

You will be invited to participate in a clinical study titled “Long term neurobehavioral effects of anesthetics and cochlear implantation on infants with hearing impairment”. Since 2001, our team has been engaged in newborn hearing screening, diagnosis and treatment, covering 21 provinces (cities, districts) and 367 counties, and nearly 3.5 million newborns were benefited. After strict pre-operative examination and screening, the infants who meet the operation criteria are scheduled to received cochlear implantation, and the infants who receive the operation are exposed to general anesthesia. The long-term neurobehavioral effects of anesthetics have always been one of the concerns of clinical and basic scientific research. From the long-term clinical observation and research in our hospital, it can be seen that the implantation of extremely severe acoustic neuropathy deaf in the early stage of infants can greatly improve their speech, social and learning abilities, and make positive benefit to the long-term behavioral development. This study relies on the rich experience of clinical anesthesia and basic research of children in our hospital, the strong professional advantages of our special hearing impairment diagnosis and treatment center, and the long-term support of national and municipal projects. By observing the long-term behavioral changes of hearing-impaired infants after receiving unilateral or bilateral cochlear implant and general anesthesia, we aim to provide a theoretical basis for the effects of cochlear implantation and anesthesia on neurobehavioral development.

1. Purposes

This study is to observe the change of perioperative period folic acid concentration in hearing-impaired infants receiving unilateral or bilateral cochlear implantation under general anesthesia, while long-term Gesell developmental scale will be followed up.

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 child. We will take 2ml of arterial blood before and after surgery. The total blood volume is within the clinical safety range, which will not increase the risk and will not harm the life surgery, and will not harm the life safety of children. In addition, blood is taken through the original venous access without additional trauma. without additional trauma. We will take charge of the detection of serological indicators serological 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 Gesell developmental scale measurement once preoperative and twice postoperative for free.

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: