Informed Consent

Project name: Application of severe ultrasound in fluid resuscitation of neonatal septic shock

leading unit: Guangdong Second Provincial General Hospital

project leader: Zhenyu Liang

Department: Pediatrics

Research period: January 1,2022 to December 31,2023

NCT No.: none.

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Version Date: November 29, 2021

Informed consent

Application Department : Pediatrics
Main researcher : Liang Zhenyu
Project name : Application of severe ultrasound in fluid resuscitation of neonatal septic shock

Dear Ms / Sir :

We will carry out a study on the application of severe ultrasound in fluid resuscitation of neonatal septic shock, and invite you to participate in the study. This study has been approved by the Ethics Committee of the Second People 's Hospital of Guangdong Province.

Please read this informed consent form as carefully as possible before you decide whether to participate in the study. It helps you understand the study and why it was conducted, the process and duration of the study, and the benefits, risks, and discomforts that may result from participating in the study. If you wish, you can also discuss it with your relatives and friends, or ask your doctor for an explanation to help you make a decision. If you are participating in other studies, please inform the researchers.

1. Research background and purpose

1.1 Disease burden and treatment status

Sepsis, especially the development of septic shock, is one of the most important causes of neonatal morbidity and mortality. Although the understanding of the pathophysiology of septic shock is evolving, the treatment of neonatal septic shock remains challenging. At present, non-invasive monitoring and clinical experience are mainly used to judge the organ function and volume status of patients and then treat them. However, there is still a lack of relevant research in the field of fluid resuscitation of neonatal septic shock.

1.2 Purpose of the study

1.Main objective : To study the application value of severe ultrasound and non-invasive cardiac output technique in fluid resuscitation of neonatal septic shock.

2.Secondary purpose : To promote the therapeutic effect of neonatal septic shock and enrich the application field of clinical ultrasound technology.

1.3 The number of participants in the study and the number of subjects expected to be included

In this study, children with neonatal septic shock diagnosed in the neonatal intensive care unit of the Second People 's Hospital of Guangdong Province from January 1,2022 to December 31,2023 were included in the population. According to the different monitoring methods used in conventional / clinical shock treatment, 30 cases

of severe ultrasound-assisted fluid resuscitation, NICOM-assisted fluid resuscitation and conventional fluid resuscitation were collected, a total of 90 cases.

2. The content and process of participating in the study

If you agree to participate in this study, the next things you need to cooperate with the researchers are as follows :

In the course of the study, we need to collect your relevant data, including : collect the demographic data, blood test and microbiological examination data of these three groups at admission. The fluid volume, blood lactic acid, blood pressure, vasoactive drugs (such as dopamine and epinephrine / norepinephrine), mechanical ventilation, renal replacement therapy and antibiotic use before fluid resuscitation were collected. The cumulative fluid infusion volume during fluid resuscitation (6 hours), and the use of vasoactive drugs and mechanical ventilation for 6 hours were collected. NICU hospitalization time and cumulative hospitalization time and mortality were collected. The time point for collecting data information is during hospitalization. The relevant data information is only used for the study of this project / The collected specimens will be used for current or future medical research.

3. Possible benefits of research

The results of this study may not have direct guiding significance for your treatment. However, the detection and analysis of your relevant data information may have a certain guiding role in the selection of your future treatment options, evaluation of efficacy, and prognosis prediction. If the test results suggest the need to adjust your medical plan, we will promptly feedback to you, by your attending physician to guide your individualized treatment (if there is no impact, we do not otherwise inform).

4. The possible risks of this project, the discomfort and inconvenience to you.

This study is an observational study that does not interfere with your clinical diagnosis and treatment process.

Non-invasive cardiac output monitoring and lung ultrasound are both non-invasive monitoring methods, and they are routine examination methods. The monitoring process has no discomfort and will not delay treatment.

The whole research process is supervised by the relevant departments of Guangdong Second Provincial General Hospital. If you encounter any questions in the research process, you can consult with the research doctor.

5、Privacy protection

Your medical records (including medical records and physical and chemical examination reports, etc.) will be kept in the hospital according to the regulations. The personal data you participated in the study and in the study are confidential, and the research results report after the study will not reveal your personal identity. Superior health / pharmaceutical / research management departments, hospital ethics committees, researchers and sponsor representatives will be allowed to consult your medical records in order to verify the procedures and / or data of clinical research. We will strictly protect the privacy of your personal medical data within the scope of existing laws.

6. Subjects ' rights

Whether to participate depends entirely on your voluntary. You can refuse to participate in this study, or withdraw from the study at any time during the study process, without any reason, which will not affect your relationship with the doctor, will not affect the loss of your medical or other interests, and you will not be discriminated against or retaliated against.

7. Related costs

The costs involved in this study are: non-invasive cardiac output monitoring, lung ultrasound examination costs.

The medical expenses are required for your routine clinical diagnosis and treatment, and the expenses are your own responsibility; the cost of noninvasive cardiac output monitoring and pulmonary ultrasound examination during the treatment was the responsibility of the research group. This study is an observational study that does not interfere with your clinical diagnosis and treatment process. This study does not increase your medical expenses.

8.Other responsible parties and compensation measures that may be related to clinical research:

This study is an observational study. The experiment will not interfere with clinical diagnosis and treatment, and the inspection methods designed during the experiment are non-invasive and will not cause damage to the body. In the course of the experiment, if the need for rescue is not suitable for continuing the experiment or the competent physician believes that the clinical condition is not suitable for continuing the experiment, we will immediately terminate the experiment and will not affect the diagnosis and treatment.

Due to the special circumstances of the patient 's damage caused by the experiment itself, the responsible party is in the experimental group. We will actively communicate with you, and bear all the losses caused by this experiment on the premise of complying with relevant national laws and regulations.

If the patient 's damage is not caused by this experiment, the relevant responsible party needs you to communicate and coordinate with the department / hospital of the diagnosis and

treatment, which is not related to the experimental group.

Finally, thank you for reading the above materials. If you decide to participate in this study, please tell your doctor that they will arrange everything about the study for you. Please keep this information. You can always find out about the information. If you need to consult and study the relevant issues, you can contact the doctor in charge. The doctor in charge contacted 020-89168212. If you have any questions about your rights and interests in this study, please contact our Ethics Committee at 020 - 89169186.

Subject Statement

I have read this informed consent form carefully, I have had the opportunity to ask questions and all questions have been answered. I understand that participation in this study is voluntary, I can choose not to participate in this study, or at any time notify the researcher to withdraw without discrimination or retaliation, any of my medical treatment and rights will not be affected. If I need another diagnosis / treatment, or if I do not comply with the trial plan, or for other reasonable reasons, the researcher may terminate my continued participation in this clinical study. I voluntarily agreed to participate in the clinical study, and I will receive a signed original ' informed consent ' (including personal reading material and informed signature page).

Signature of subject：　　date：

Contact number：

Signature of legal representative [if applicable]：

Relationship with subjects：

Contact number：

date：

Statement by researchers

I have accurately informed the subjects of the content of the informed consent form and answered the questions of the subjects. The subjects volunteered to participate in this clinical study.

Researchers signature：　　date：

Contact number：