Informed Consent

Project name: Risk factors for poor prognosis in neonatal necrotizing enterocolitis

Leading unit: Guangzhou Women and Children's Medical Center

Project leader: Wei Zhou

Department: Pediatrics

Research period: July 1, 2024 to June 30, 2025

Project number: EK-NEC20240705

NCT No.: none.

Version No.: V1.0

Version Date: July 01, 2024

Application for exemption of informed consent

Project name: Risk factors for poor prognosis in neonatal necrotizing enterocolitis

Project leader: Wei Zhou

Dear Ms / Sir :

We will carry out a study on the “Risk factors for poor prognosis in neonatal necrotizing enterocolitis: A single-center retrospective analysis”, and invite you to participate in the study. This study has been approved by the Ethics Committee of Guangzhou Women and Children's Medical Center.

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. Purpose of the study

This retrospective cohort study aims to enroll patients with necrotizing enterocolitis (NEC) from July 1, 2017 to December 31, 2022, conduct a comprehensive analysis of their clinical characteristics, metabolic indicators, laboratory parameters, prognosis, and outcomes, and identify indicators that may predict the progression of neonatal NEC and its associated mortality.

2. Possible benefits of research

All subjects enrolled in the study have no direct financial interests. However, for the neonatal sepsis patients involved in this study, pediatricians will provide professional clinical treatment recommendations to the children’s parents with the consent of the latter. Furthermore, the results of this study will help address unmet needs in the field of neonatal NEC care and improve the outcomes of NEC treatment through timely intervention.

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

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

The whole research process is supervised by the relevant departments of Guangzhou Women and Children's Medical Center. If you encounter any questions in the research process, you can consult with the research doctor.

4. 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.

5. 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.

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 +86 20 3836 7270. If you have any questions about your rights and interests in this study, please contact our Ethics Committee at +86 20 3836 7270.

Subject Statement

I have read this informed consent form carefully, have had the opportunity to ask questions, and all my questions have been answered. I understand that participation in this study is voluntary: I may choose not to participate, or notify the researchers at any time to withdraw, without facing discrimination or retaliation. My medical treatment and rights will not be affected in any way. If I require additional diagnosis or treatment, fail to comply with the trial protocol, or for other reasonable reasons, the researchers may terminate my participation in this clinical study. I voluntarily agree to participate in the clinical study, and I will receive a signed original copy of the "Informed Consent Form" (including the personal information sheet and the 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：