Informed Consent Form for Clinical Research

2025.1.1

Dear legal guardian of the child:

We invite you to participate in the study titled "Relationship Between Parenteral Nutrition and Microplastic Exposure in Neonates." This study has been reviewed and approved by the Ethics Committee of the Second Peoples Hospital of Guangdong Province. This informed consent form provides you with information to assist in your decision to participate in this study. If you agree to join this study, please read the following content carefully. If you have any questions, please contact the investigator responsible for this study.

1. Background and Objectives of the Research Project:

Microplastics refer to tiny plastic particles with a diameter of less than 5 millimeters. In recent years, with advancements in analytical techniques, microplastics have been detected in human blood, lungs, placentas, and even breast milk, confirming their systemic distribution and potential accumulation in the human body. In neonatal intensive care units (NICUs), life support and nutritional supply are highly dependent on plastic medical devices, such as intravenous infusion bags, infusion lines, injection pumps, and ventilator circuits. These devices may contain intentionally added microplastics during production or release secondary microplastics due to physical friction or chemical degradation during use. Of particular importance is that for critically ill neonates who cannot be fed orally, parenteral nutrition (PN) is their sole source of survival. However, the entire "plastic tubing" system that constitutes the parenteral nutrition delivery system represents a potential and persistent source of microplastic exposure. Studies have shown that microplastic particles can be detected in infusion solutions after passing through plastic equipment[]. This implies that neonates receiving intravenous nutrition may be exposed to a unique pattern of "iatrogenic, persistent microplastic infusion."

Clinical studies on neonatal exposure to AP remain limited. Moreover, most neonatal biomonitoring studies are based on in vitro experiments and random urine samples collected at hospital admission or discharge, without considering the time-dependent nature of exposure. Additionally, there is a lack of research on neonatal microplastic load, particularly quantitative data in blood. Therefore, this study aims to assess the current status of neonatal microplastic exposure during NICU hospitalization. Through a meticulously designed gradient exposure cohort, this study seeks to systematically evaluate and compare the microplastic load in the blood of neonates receiving long-term parenteral nutrition for the first time.

II. Research Content:

Researchers conducted face-to-face interviews to record demographic information and collected neonatal blood samples. The neonatal blood samples were divided into the following three groups: (1) Long-term exposure group (n=4): Preterm infants who required total parenteral nutrition (TPN) support for more than 14 days due to severe feeding difficulties, necrotizing enterocolitis (NEC), short bowel syndrome, or other serious intestinal diseases. (2) Short-term exposure group (n=4): Preterm infants who received TPN support for 3 to 7 days due to early adaptation issues (e.g., respiratory distress, transient feeding intolerance) and had successfully transitioned to total enteral nutrition (TEN) for at least 48 hours prior to blood sample collection. This group represents the common, transient, and routine iatrogenic exposure in NICUs. Control group (n=4): Healthy full-term neonates with a gestational age ⩾37 weeks. These neonates did not receive any intravenous nutrition support or planned fluid therapy, and were used to establish baseline microplastic levels in the absence of relevant iatrogenic exposure. This study strictly adhered to the ethical guidelines of the Declaration of Helsinki, and the research protocol was approved by the Medical Ethics Committee of the Second Affiliated Hospital of Guangdong Province, Jinan University.

三、Cost statement:

The research-related expenses are covered by this study project, and you are not required to bear any costs.

四、Potential benefits of participating in this study:

This study may not provide direct benefits, but the project will contribute to evaluating and comparing the microplastic load in the blood of neonates receiving long-term parenteral nutrition, thereby exploring a novel approach for refined neonatal care.

V. Potential Risks and Mitigation Measures

This study employs mature research methodologies, with a well-designed and feasible research protocol, and is conducted under favorable research conditions.

6. Your Rights:

Your participation in the trial is entirely voluntary. You may withdraw from the trial at any time without justification, and this will not affect your relationship with medical staff or future diagnosis and treatment.

VII. Privacy Issues

If you decide to participate in this study, your participation in the trial and your personal data during the trial will be kept confidential. Your medical records will be stored in the hospital. To ensure the study is conducted in accordance with regulations, government authorities or members of the ethics review committee may, when necessary, be permitted to access your personal data at the study site. Any public reports regarding the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the limits permitted by law.

8. Contact Information

For any inquiries regarding this study, please contact the study lead: Xu Debo at 15625852418, or the Hospital Ethics Office at 020-89169186.

Note: This informed consent form is printed on both sides and prepared in triplicate, with one copy for the subject, one for the investigator, and one for the medical record.

Statement of consent by legal guardian:

I have read the above introduction regarding this study and fully understand the potential risks and benefits associated with participation in this research. I voluntarily consent to participate in the clinical study described herein.

Signature of legal guardian (regular script):

Subject relationship:

contact number ：

date ：

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The investigators declare:

I confirm that the legal guardian of the child has been fully informed of the details of this study, particularly the potential risks and benefits associated with participation.

Researchers name (regular script):

contact number ：

date ：