Second People's Hospital of Guangdong Province
informed consent

Department: Pediatrics

Lead researcher: Li Huiyi

Project Title: A Study on the Clinical Value of Position Management Guided by Lung Ultrasound in Neonatal Ventilator-Associated Pneumonia

Personal reading materials

Dear Sir/Madam:

We will conduct a study on the application value of lung ultrasound-guided position management in neonatal ventilator-associated pneumonia. You are invited to participate in this study, which has been approved by the Ethics Committee of Guangdong Second People's Hospital.

Before deciding to participate in this study, please read this informed consent form carefully. It will help you understand the study's purpose, procedures, duration, potential benefits, risks, and possible discomforts. If you'd like, discuss the details with family or friends, or ask your doctor for clarification to make an informed decision. If you're currently enrolled in another study, please inform the researchers.

1. Research Background and Objectives

1.1 Burden of disease and current treatment status

Ventilator-associated pneumonia (VAP) is one of the severe complications in ventilator therapy. Currently, mechanical ventilation is widely used in neonatal intensive care units, and the incidence of neonatal VAP has significantly increased. The occurrence of neonatal VAP not only raises mortality rates but also prolongs hospital stays, increases treatment costs, and adds financial burdens to families. Position management, as the most fundamental aspect of neonatal care, has been proven effective in reducing ventilator-associated pneumonia through proper positioning practices. However, there are currently no specific operational standards for position management both domestically and internationally. Clinical practice often relies on

empirical approaches, lacking personalized positioning strategies. Pulmonary ultrasound, a non-invasive diagnostic tool, has become extensively utilized for diagnosing neonatal lung diseases and monitoring the severity of pulmonary abnormalities.

1.2 Research Objectives

Primary objective: To evaluate the clinical value of conventional positioning management versus lung ultrasound-guided positioning management in neonatal ventilator-associated pneumonia (VAP).

Secondary objective: To promote the recovery of neonatal VAP and expand the clinical application of ultrasound technology.

1.3 Number of participating institutions and subjects expected to be included

This study enrolled newborns diagnosed with ventilator-associated pneumonia (VAP) in the Neonatal Intensive Care Unit of Guangdong Provincial Second People's Hospital between April 1, 2024 and March 31,2026. Based on different postural management methods at that time, 40 cases each were collected for routine posture management and pulmonary ultrasound-guided posture management, totaling 80 cases.

2. Content and process of participation in the study

If you agree to participate in this study, you will be asked to cooperate with the researchers to complete the following tasks:

During the study, we will collect relevant data including blood gas analysis, oxygenation index, and pulmonary ultrasound scores. We will also document the experimental subjects' ventilator usage, hospitalization duration, and complications. The data collection will be conducted during their hospital stay, and all collected information will be exclusively used for this research project. The specimens obtained will be utilized for current medical research purposes.

3. Research on possible benefits

The findings of this study may not directly guide your current treatment. However, by analyzing your relevant data,

The test results may guide your future treatment plan selection, efficacy evaluation, and prognosis prediction. If the findings suggest adjustments to your medical regimen, we will promptly inform you and your attending physician to guide personalized treatment (we will not notify you separately if no changes are needed).

4. Possible risks of the project and discomfort and inconvenience caused to you

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

Pulmonary ultrasound is a non-invasive monitoring method and a routine examination method. There is no discomfort during the monitoring process, and the treatment will not be delayed.

 Version: 2.0 Version Date: 2023-11-21

The whole study process is supervised by the relevant department of Guangdong Second People's Hospital. If you have any questions during the study, please consult the research doctor.

5. Privacy

Your medical records (including study medical records and laboratory reports) will be securely stored in the hospital in accordance with regulations. All personal information related to your participation in the study will remain confidential, and the final research report will not disclose your personal identity. Authorized personnel from higher-level health/Pharmaceutical/Research regulatory authorities, hospital ethics committees, investigators, and sponsor representatives may access your medical records to verify clinical trial procedures and/or data. We will strictly protect your personal medical information privacy in compliance with applicable laws.

6. Rights of subjects

Participation is entirely voluntary. You may decline to take part in this study or withdraw at any time without cause. This will not affect your relationship with your doctor, nor will it result in any loss of medical care or other benefits. You will not be subjected to discrimination or retaliation.

7. Related costs

The costs involved in this study are: pulmonary ultrasound examination costs.

The medical expenses for your routine clinical diagnosis and treatment are your own responsibility, while the pulmonary ultrasound examination during the treatment process is covered by the research team.

This is an observational study that does not interfere with your clinical treatment and does not add to your medical costs.

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

This observational study does not involve clinical interventions. All procedures are non-invasive and pose no physical harm. Should rescue measures be required during the trial, or if the attending physician deems the patient's condition unsuitable for continued participation, we will immediately terminate the experiment without affecting ongoing medical care.

In the special case where the patient is harmed due to the experiment itself, the responsible party is in the experimental group. We will actively communicate with you and bear all the losses caused by the experiment under the premise of complying with relevant national laws and regulations.

If the patient's injury is not caused by this experiment, the relevant responsible party requires you to communicate with the department/hospital where the diagnosis and treatment was undertaken.

Coordination, unrelated to the experimental group.

Finally, thank you for reading this information. If you decide to participate in this study, please inform your doctor, who will arrange all necessary procedures. Please keep this document for future reference. You may access any updates at any time. For inquiries about the study, contact your attending physician at 020-89168212.

If you have any questions about your rights in this study, please contact the Ethics Committee of this center at the following phone number:

020-89169186。

Subject Statement

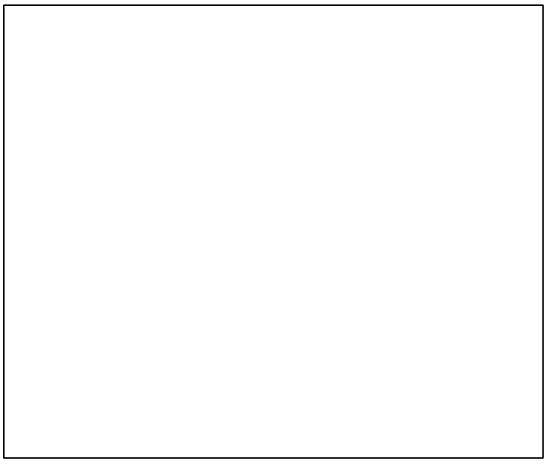
I have carefully read this informed consent form. I have the opportunity to ask questions, and all questions have been answered. I understand that participation in this study is voluntary. I may choose not to participate or withdraw at any time after notifying the investigator without facing discrimination or retaliation. My medical treatment and rights will not be affected by this decision.

If I need another diagnosis/therapy, or I do not comply with the trial protocol, or for other reasonable reasons, the investigator may discontinue my participation in this clinical study.

I voluntarily agree to participate in this clinical study and will receive an original signed "Informed Consent" (including personal reading materials and subject declaration page).

 Version: 2.0 Version Date: 2023-11-21

Subject footprints:



Parent of the subject signature: Date:
Parent signature of the subject: Date:

contact number：

Signature of legal representative [if applicable]:
Contact number:

Subject relationship: Date:

Researcher Statement

I have accurately informed the subject of the informed consent and answered the subject's questions, and the subject voluntarily participated in this clinical study.

Researcher's signature: Date:

contact number：