Official Title: Non-Invasive Detection of Aspergillosis in Ventilated Patients: Galactomannan Analysis in Exhaled Breath Condensate

Short Title: Aspergillosis Detection via EBC-GM in Ventilated Patients

NCT Number: Pending

Study Duration: January 2, 2023 - January 10, 2024

Funding Source: Sichuan Provincial People's Hospital

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Informed Consent Form

Research Project: Non-Invasive Detection of Invasive Aspergillosis in Mechanically Ventilated Patients: Galactomannan Analysis in Exhaled Breath Condensate

Research Purpose: This study aims to provide a non-invasive diagnostic method for Invasive Pulmonary Aspergillosis (IPA) in mechanically ventilated patients by evaluating the levels of Galactomannan (GM) in Exhaled Breath Condensate (EBC).

Study Process: Participants will collect one EBC sample (about 1ml) using a self-designed EBC collection device. The collection process, expected not to interrupt mechanical ventilation, will maintain the patient's vital signs stable and take about 30 minutes. We will record changes in heart rate, blood pressure, respiration, oxygen saturation, ventilator settings, and blood gases before and after collection. A bronchoscopy to obtain Bronchoalveolar Lavage Fluid (BALF) (about 3-5ml) will also be performed on the same day as EBC collection.

Possible Risks and Discomfort: During EBC collection, participants may experience the following side effects, though rare:

1. Sensation of dryness or cold in the airway.
2. Increased or decreased heart rate.
3. Increased or decreased breathing rate.
4. Other unforeseeable situations Note that these side effects are usually temporary and will quickly disappear after the collection process. Any changes in breathing or heart rate exceeding 20% of the baseline value will terminate the collection.

Data Collection and Privacy: All participant information will be kept confidential, and study results will be reported anonymously, ensuring participants' privacy rights are not violated.

Voluntary Participation: Participation in this study is entirely voluntary. Participants will be fully informed about the study both before and after the collection of Exhaled Breath Condensate (EBC), and they retain the right to withdraw their consent and exit the study at any point, without any impact on the medical care or rights they are entitled to receive.

Follow-up Period: After collecting the EBC, vital signs will be closely monitored for 72 hours, followed by routine follow-up for 14 days, with daily recording of changes in vital signs.

Consent Statement I have read the above information, fully understood the study process, possible risks and discomforts, data collection, and privacy protection. I voluntarily participate in this study and allow my vital signs and blood gas changes data to be used for research purposes.

Patient or Authorized Family Member's Signature: _____ Date: _____
Conversing Doctor's Signature: _____ Date: _____

*This study has been submitted to and approved by the Ethics Review Committee of Sichuan Provincial People’s Hospital, affiliated with Sichuan Academy of Medical Sciences (Approval No. 2023-144). All study participants will undergo a detailed informed consent process to ensure they fully understand the study's purpose, process, potential risks, and benefits, and are aware of their right to withdraw from the study at any time.

If participants have any questions about this study, please feel free to contact the study team doctor (Project Leader: Lin Chen, 18111585286).