

Official Title: Risk of Aspergillus infection in patients with chronic structural lung disease

Short Title: Risk of Aspergillus infection in patients with chronic lung disease

NCT Number: Pending

Study Duration: July 1, 2022 - January 31, 2024

Funding Source: Sichuan Provincial People's Hospital

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Document Date: January 31, 2024

Informed Consent Form

Research Project: Risk of Aspergillus infection in patients with chronic structural lung disease.

Research Purpose: This study aims to identify the risk factors associated with fungal infections and to investigate acute exacerbation in these patients.

Study Process:

Participants will undergo the following procedures:

- Sputum Microscopy and Culture: To check for the presence of Aspergillus.
- High-Resolution Computed Tomography (HRCT) of the Chest: To obtain detailed images of the lung structure.
- Blood Tests: Including tests for Aspergillus-specific IgG and IgM antibodies and serum galactomannan (GM).

The data from patients diagnosed with Aspergillus infection will be compared to those with Aspergillus colonization to understand risk factors better.

Possible Risks and Discomfort:

Participants may experience minor side effects during blood collection:

- Pain: Brief pain during needle insertion.
- Bleeding: Minor bleeding at the puncture site.

- Infection: Rare, as strict sterilization protocols are followed.
- Other unforeseeable situations: Any severe reaction will lead to immediate cessation of the procedure.

Data Collection and Privacy: All personal information will be confidential. Results will be anonymized to protect participant privacy.

Voluntary Participation: Participation is voluntary, and participants can withdraw at any time without affecting their medical care or rights.

Follow-up Period and Benefits:

- Free Diagnostic Testing: Participants will receive free testing for Aspergillus-specific IgG and IgM antibodies, with each participant eligible for at least two free tests. Additional tests during the follow-up period may be requested by the overseeing physician based on treatment progress, at no cost to the participant.
- Free Outpatient Follow-up Visits:
 - One-Month Follow-up: All participants will benefit from free follow-up visits at our outpatient clinic for one month after initial participation. These visits are designed to monitor health outcomes and provide ongoing support.
 - Extended Six-Month Follow-up for Positive Cases: Participants who test positive for Aspergillus infection will receive an extended follow-up period of six months. During this time, they will continue to have free access to monthly outpatient follow-up visits, ensuring comprehensive monitoring and care throughout their treatment course.

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 blood test 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. Lun Audit (Research) 2023-482). 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).