

Non-Invasive Diagnosis of Pediatric Pulmonary Invasive Mold Infections

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 120 days to 21 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Males or females age > 120 days and < 22 years at any participating site
- Have at least one of the following conditions associated with a known high incidence of IFI: hematopoietic stem cell transplantation (HSCT), aplastic anemia, bone marrow failure, primary or acquired immune deficiency, or malignancy
- New (last 96 hours) radiographic evidence of at least one of the following: at least one nodular lesion greater than or equal to 5 mm in size, a wedge-shaped and segmental or lobar consolidation, a cavitary lesion, a lesion with a halo sign, a lesion with a reverse halo sign, or a lesion with an air crescent sign
- Prolonged neutropenia (absolute neutrophil count < 500 cells/μl for a period of ≥ 5 consecutive days) in 30 days prior to and including the day of qualifying chest MRI or CT scan date OR currently receiving systemic therapy for acute or chronic graft-versus-host disease (GVHD) OR presence of neutrophil dysfunction because of underlying acquired or primary immune deficiency (e.g. chronic granulomatous disease) on the date of the qualifying chest MRI or CT scan
- Subject consent or parental/guardian permission (informed consent) and if appropriate, child assent

Exclusion Criteria:

- Weight <3 kg, so as to not exceed 3 ml/kg in a single blood draw
- Previous inclusion in this study

Conditions & Interventions

Interventions:

DIAGNOSTIC_TEST: Non-Invasive Testing for PIFI

Conditions:

Pulmonary Invasive Fungal Infections, Pulmonary Invasive Aspergillosis

More Information

Description:

This study will establish a non-invasive diagnostic approach and evaluate clinical outcomes for children at high-risk for pulmonary invasive fungal infection (PIFI).

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Principal Investigator:

Principal Investigator ID:

Phase:

IRB Number:

System ID: NCT03827694

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