Comparison of Uncomplicated Candidemia Therapy Duration in Children

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 4 month(s) and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Age > 120 days at the time of the first negative blood culture at any participating site;
2. Candidemia with at least one positive blood culture for any Candida spp;
3. Receiving/received an echinocandin (caspofungin, micafungin, anidulafungin, or rezafungin) as primary antifungal therapy for candidemia for at least 2 days from day of first negative culture with continuation of uninterrupted systemic antifungal therapy at the time of enrollment);
4. Sustained clearance of Candida spp. defined as negative blood culture(s) obtained after onset of candidemia and before day of randomization;
5. Partial or complete clinical response, as defined by published guidelines (Table 5), on or before day of randomization;
6. Between the onset of qualifying candidemia and randomization, no suspicion of disseminated candidiasis by patient's clinical team or, if deemed clinically necessary, documented negative radiological imaging such as an abdominal ultrasound or abdominal CT scan.

Exclusion Criteria:

1. Already receiving antifungal therapy for a previously diagnosed systemic invasive fungal disease;
2. Neutropenic (absolute neutrophil count < 500 cells/µl) at the time of enrollment or anticipated to be neutropenic in the week following randomization;
3. Have an underlying condition that requires them to be on antifungal prophylaxis when not receiving directed therapy for an invasive fungal disease;
4. Previous enrollment in this trial;
5. Females of childbearing age with a current pregnancy diagnosis or without a negative pregnancy test for their current admission;
6. A documented DNR order;
7. Have an implantable cardiac device (e.g., ventricular assist device, pacemaker)

Conditions & Interventions

Interventions:
OTHER: therapy duration
Conditions:
Invasive Candidiasis

More Information

Description:
The goal of this clinical trial is to compare antifungal therapy duration in pediatric uncomplicated candidemia. The specific aims are: * Compare the desirability of outcome ranking in children with uncomplicated candidemia randomized to 7 additional days of antifungal therapy (standard-course) versus no additional antifungal therapy (short-course) after already receiving 7 days of echinocandin therapy. * Compare the 14-day desirability of outcome measure for subjects with a negative and those with a positive T2Candida® biomarker at day 7 of therapy within randomized groups. Participants meeting eligibility criteria will be approached and consented between day 5 and 7 of primary systemic antifungal therapy. On day 7 of primary systemic antifungal therapy, inclusion and exclusion criteria will again be reviewed for consented patients and those still eligible will be randomized 1:1 to the two study arms. Researchers will compare no additional antifungal therapy (short-course) versus 7 additional days of systemic antifungal therapy (standard-course) in pediatric patients with uncomplicated candidemia who have already received 7 days of primary systemic antifungal therapy to see if shorter durations are as effective as longer durations in treating uncomplicated candidemia.

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