



BMT CTN PROTOCOL #0101

A Randomized Double-blind Trial of Fluconazole vs. Voriconazole for the Prevention of Invasive Fungal Infections in Allogeneic Blood and Marrow Transplant Patients

Clarification to Version 6.0 of the Protocol:

The definition of a “presumptive fungal infection” in *Table 3.1.1a Definitions of Invasive Fungal Infections in Patients with Cancer and Recipients of Hematopoietic Stem Cell Transplants* was expanded to include the second bullet below as indicated in bold italicized text. Note that a presumptive infection is considered an invasive fungal infection meeting the endpoint.

A “presumptive fungal infection” must have:

- At least 1 host criterion (see Table 3.1.1.1b) and 1 clinical criterion for lower respiratory tract infection as listed below. A microbiological criterion is NOT required. The clinical criterion for lower respiratory tract infection must be consistent with the microbiological findings, if any, temporally related to current episode and other potential causes must have been eliminated, along with:
 - The presence of one of the following “specific” imaging signs on CT: (1) halo sign, (2) wedge-shaped infiltrate, (3) air crescent sign OR
 - The presence of a new non-specific focal infiltrate, PLUS at least one of the following: pleural rub, pleural pain, or haemoptysis AND no evidence of other etiology demonstrated by bronchoscopic examination
- ***Or if lacking a host criterion, but otherwise meets the microbiological and clinical criteria for a presumptive, probable or proven invasive fungal infection. The clinical criterion for lower respiratory tract infection must be consistent with the microbiological findings, if any, temporally related to current episode and other potential causes must have been eliminated, along with:***
 - ***The presence of one of the following “specific” imaging signs on CT: (1) well-defined nodule with or without a halo sign, (2) halo sign, (3) wedge-shaped infiltrate, (4) air crescent sign, (5) cavity within area of consolidation OR***
 - ***The presence of a new non-specific focal infiltrate, PLUS at least one of the following: pleural rub, pleural pain, or haemoptysis AND no evidence of other etiology demonstrated by bronchoscopic examination***