Public Title	Dose escalation study: caspofungin in invasive aspergillosis
Scientific Title	A phase II dose escalation study of caspofungin in patients with invasive aspergillosis
Short Title	SC Caspofungin in aspergillosis
Id KN/ELN	LN_AGIHO_2006_222
Trialgoup	AGIHO
Type of Trial	multicentric
Phase	Phase II
Disease	Miscellaneous(Miscellaneous) Supportive Care
Stage of Disease	not specified / all stages

Inclusion Criteria

- Immunocompromised due to hematologic malignancies, bone marrow failure syndromes, hematopoietic stem cell transplantation, solid organ transplantation, other conditions resulting in severe neutropenia, HIV infection, prolonged corticosteroid therapy (20 mg Prednisone or equivalent for 3 weeks), treatment with other immunosuppressive medications, or other immunocompromising conditions that place patients at risk for invasive fungal infections (IFIs).
- Evidence of proven or probable invasive aspergillosis, by modified EORTC criteria (see chapter 17.1 for modified criteria)
- Indwelling central venous catheter (double lumen is desirable) for administering drugs and obtaining plasma samples.
- Female patients of childbearing age must have a negative pregnancy test at study entry and take adequate contraceptive measures throughout the study.
- Written informed consent given by the patient or his/her legal guardian prior to enrollment in the study.

Exclusion Criteria

- Pregnant or breast-feeding female patients.
- Patients with the following pathological laboratory findings: Serum bilirubin > 3x upper limit of the age-adjusted normal range; SGOT or SGPT > 5x the upper limit of the age -adjusted normal range; Alkaline phosphatase > 5x the upper limit of the ageadjusted normal range
- Patients who have undergone hematopoietic stem-cell transplantation with clinical or laboratory evidence of active veno-occlusive disease (VOD). VOD is characterized by early elevation of serum transaminases and subsequent persistent elevation of serum bilirubin, tenderness of the liver, increase in body weight, and ascites.
- Hemodynamically unstable patients or patients with an expected survival time of less than 5 days
- Patients previously enrolled in the study.
- Patients with concomitant diseases or conditions which, in the opinion of the principle investigator, could distort the results of the study or which could entail an additional risk for a patient receiving the study medication.
- Patients concurrently receiving efavirenz, nevirapin, rifampicin,dexamethasone, phenytoin, carbamazepine, phenobarbital or cyclosporin A
- Patients with a documented history of intolerance to echinocandin antifungal agents.
- Concomitant other systemic antifungal agents are not permitted on study.
- Chronic invasive fungal infection, defined as signs/symptoms of invasive fungal infection present for > 4 weeks preceding entry into study
- Prior systemic therapy of 4 days with any polyene anti-fungal agent within 14 days of study enrollment

- Prior systemic therapy of 4 days with non-polyenes (i.e., azole or echinochandin derivatives) for the current, documented IFI. (Prior systemic anti-fungal therapy with azole derivatives for prophylaxis or as empiric therapy for febrile neutropenia is permissible.)
- Patients possibly dependent on the sponsor or investigator

Age	All ages
Status	Closed
start of Recruitment	01.12.2006
Recruiting countries	Germany
Target Sample Size	32
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Centre of Trial	Universitätsklinikum der Universität zu Köln
Sponsors	Universitätsklinikum der Univesität zu Köln