

Public Title	Liposomales Amphotericin B in antifungal primary prophylaxis in ALL
Scientific Title	ProphyALL - Pilot study on safety of four weekly administrations of 7 mg/kg of liposomal amphotericin B (AmBisome?) in antifungal primary prophylaxis treatment of elderly patients with acute lymphoblastic leukemia undergoing induction chemotherapy within the GMALL-Elderly protocol
Short Title	ALL ProphyALL
Id KN/ELN	LN_GMALL_2007_238
Trialgroup	GMALL
Type of Trial	multicentric, single-group, open-label
Phase	Phase II
Disease	Miscellaneous(Miscellaneous) Supportive Care Acute lymphoblastic leukemia(ALL) All subtypes
Stage of Disease	de novo/non-treated
Aim	- Safety of prophylactic 4-weekly intravenous doses of liposomal amphotericin B (AmBisome) à 7 mg/kg
Outcomes	- incidence of fungal infections according to EORTC within 12 weeks after onset of prophylaxis (Primary Outcome)
Inclusion Criteria	- male or female patients with acute lymphoblastic leukemia during the two first induction cycles - according to the GMALL Elderly 1/2003 study-protocol
Exclusion Criteria	- active or estimated fungal infection - previous systemic fungal infection - patient without sufficient renal- and liver-function
Age	>=55 years
Status	Closed
start of Recruitment	01.05.2007
Recruiting countries	Germany
Target Sample Size	20
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Other Registers

ClinicalTrials.govNCT00386997
Deutsches Leukämie Studienregister - KompetenzenetzLN_GMALL_2007_238 (Primary Register)

Interventions

- Amphotericin B : weekly administrations of 7 mg/kg

Remark

Complementary study to the GMALL Elderly 01/2003 protocol