European LeukemiaNet
SHORTPROTOCOL
ALL GMALL Allo-SCT-Treo-VP16-Cyclo in ALL

Public Title	Allogeneic Stem Cell Transplantation with Treosulfan, VP-16 and Cyclophosphamide for patients with ALL
Scientific Title	Allogeneic Stem Cell Transplantation with Treosulfan, VP-16 and Cyclophosphamide for patients with Acute Lymphoblastic Leukemia (ALL) not eligible for TBI-containing regimen: A phase II study
Short Title	ALL GMALL Allo-SCT-Treo-VP16-Cyclo in ALL
Id KN/ELN	LN_GMALL_2007_278
Trialgoup	GMALL
Type of Trial	multicentric
Phase	Phase II
Disease	Acute lymphoblastic leukemia(ALL) Stem cell transplantation Stem cell transplantation(SCT) ALL
Stage of Disease	.
Aim	- The present study will be a multicenter, prospective phase II-study investigating safety and efficacy of the combination of treosulfan, etoposide, and cyclophosphamid as conditioning regimen for patients with acute lymphoblastic leukemia who are not eligible for a TBI-containing regimen
Outcomes	- Evaluation of engraftment day 28 and non-relapse mortality at day 100 and at 1 year after allogeneic stem cell transplantation (Primary Outcome) - Incidence of aGvHD day 100 acc. Glucksberg scale - Incidence of cGvHD accSeattle criteria - Toxicity acc. NCI-CTCAE V3.0 - Cumulative Incidence of relapse 2 years - DFS 2 years - OS 2 years
Inclusion Criteria	- Acute lymphoblastic leukemia in first or subsequent remission - Indication for allogeneic stem cell transplantation acc. To the actual protocol of the German Acute Lymphoblastic Leukemia Study Group - Patient’s age: 18-65 years - HLA-identical or compatible related or unrelated donor - Not eligible for total body irradiation - Patient’s written informed consent - Adequate contraception
Exclusion Criteria	- No complete remission at time of registration - Severe irreversible renal, hepatic, pulmonary or cardiac disease - Positive serology for HIV - Pregnant or lactating women - Severe florid infection - Experienced Hypersensitivity against the study drug - Cystitis - obstructive renal function - Participation in any other clinical drug trial - Serious psychiatric or psychological disorders - Progressive invasive fungal infection at time of registration
Age	<= 65 years

Status	Closed
start of Recruitment	06.07.2007
Recruiting countries	Germany
Target Sample Size	55
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Sponsors	Universitätsklinikum Eppendorf
Other Registers	ClinicalTrials.govNCT00682305 (Primary Register) European Clinical Trials Database - EUDRACT2006-003566-34
Interventions	- Treosulfan : according to protocol - Etoposide : according to protocol - Cyclophoshamide : according to protocol
Therapy	On day -7 to -5 Treosulfan is given in a dosage of 12 g/m² followed by Etoposide on day -4 in a dosage of 30 mg/kg BW and Cyclophophamide on day -3 and -2 at a dosage of 60 mg/kg BW