European LeukemiaNet
SHORTPROTOCOL
OSHO#069 2004

Public Title	Comparison of the OSHO Protocol to a Standard Arm Protocol of the German AML Intergroup in Patients With AML > 60 years
Scientific Title	Randomized phase III study comparing the OSHO arm to the standard intergroup arm Efficacy of allogeneic stem cell transplantation in comparison to a second consolidation chemotherapy in elderly patients with newly diagnosed AML in the age over 60 years
Short Title	OSHO#069 2004
Id KN/ELN	LN_OSHO_2005_231
Trialgoup	OSHO
Type of Trial	multicentric, randomized
Phase	Phase III
Disease	Acute myeloid leukemia(AML) Stem cell transplantation Acute myeloid leukemia(AML) AML all subtypes without FAB M3
Stage of Disease	de novo/non-treated
Aim	- comparison of event free survival (OSHO arm versus Standard intergroup arm) - valence of intensive consolidation regime, compared to historic controls - comparison of consolidation regime versus allogenetic stemcelltransplantation with reduced conditioning - results under palliative and supportive care
Outcomes	- Ereignisfreies Überleben (EFS) im kurativ intendierten Therapieansatz Comparison of event-free survival: OSHO arm versus standard intergroup arm (Primary Outcome) - CR Rate CR rate - Gesamtüberleben (OS), rezidivfreies Überleben (RFS), behandlungsassoziierte Toxizität und Mortalität (TRM), OS nach allogener SCT mit verwandten und unverwandten Spendern, Erfassung der Bedeutung von Komorbiditäten und IADL für die Therapieentscheidung overall survival, relapse-free interval and transplant related mortality after allogeneic stem cell transplantation with reduced intensity conditioning compared to conventional treatment
Inclusion Criteria	- Patients of both sexes with age > 60 years and newly diagnosed acute myeloid leukaemia as defined by new WHO classification - written informed consent
Exclusion Criteria	- pretreatment of leukemia - no informed consent - simultaneous inclusion in other studies - mental disability - contraindication for intensive chemotherapy - AML FAB M3 - contraindication for allogeneic stem cell transplantation - restriction of following organ functions: - creatinine-clearance < 50 ml/min - cardiac ejection fraction < 40 % - severe pulmonary restriction - bilirubin > 2x ULN; SGOT and SGPT > 4x ULN - uncontrolled hypertension - severe uncontrolled metabolism disturbance - Karnofsky-performance-score < 70% - hepatitis C

	- other malignancy - age of unrelated donor >70 years and - age of related donor >75 years
Age	> 60 years
Status	Active
start of Recruitment	01.04.2005
Recruiting countries	Germany
Target Sample Size	330
Leader	Niederwieser, Prof. Dr. med. Dr. h.c., Dietger Universitätsklinikum Leipzig AöR Abt. Hämatologie und Internistische Onkologie Johannisallee 32a 04103 Leipzig Tel: +49 (0)341 971 3050 Fax: +49 (0)341 971 3059 Email: dietger@medizin.uni-leipzig.de
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Centre of Trial	Universitätsklinikum Leipzig
Diagnostics	**Cytogenetics** Zytomorphologisches Labor der Med.Klinik II, Universität Leipzig **Morphology** Zytomorphologisches Labor der Med.Klinik II, Universität Leipzig
Qualitymark	German Cancer Organization
Sponsors	Universitätsklinikum Leipzig
Supporters	Universitätsklinikum Leipzig
Other Registers	ClinicalTrials.govNCT01497002
Interventions	- Stem cell transplantation : according to protocol