Public Title	HCT Versus CT in Elderly AML
Scientific Title	Randomized Phase III Study Comparing Conventional Chemotherapy to Low Dose Total Body Irradiation-Based Conditioning and HCT From Related and Unrelated Donors as Consolidation Therapy for Older Patients With AML in 1st Complete Remission
Short Title	HCT vs CT
Id KN/ELN	LN_OSHO_2012_507
Trialgoup	OSHO
Type of Trial	multicentric, randomized, prospective, open-label, double-group
Phase	Phase III
Disease	Acute myeloid leukemia(AML) Stem cell transplantation
Stage of Disease	.
Aim	- Efficacy of allogeneic related or unrelated hematopoietic cell transplantation (HCT) after reduced intensity conditioning as a consolidation treatment for elderly patients with AML in complete remission. - Safety and toxicity of allogeneic related and unrelated HCT vs CT in elderly AML final 5.1, 2013-11-07 incl amendments 01-03 10 / 75 EBMT hematopoietic cell transplantation (HCT) after reduced intensity conditioning as a consolidation treatment for elderly patients with AML in complete remission.
Outcomes	- To evaluate Leukaemia Free Survival (LFS) after allo HCT in AML/RAEB in complete remission using matched or unrelated donors in comparison to conventional chemotherapy 5 years (Primary Outcome) - To evaluate overall survival, relapse, Treatment Related Mortality (TRM) and complications after HCT 5 Years
Inclusion Criteria	- Age >= 60 years and <= 75 years - primary or secondary AML as defined by WHO or refractory anemia with excess of blasts (RAEB) - First complete remission following one or two cycles of induction chemotherapy - Chemotherapy was administered according to current participating cooperative group protocols - Karnofsky score >= 70 - Written informed consent
Exclusion Criteria	- AML FAB M3 - HIV positivity - Participation in another clinical trial without prior consent of the coordinating investigator, patients may exceptionally take part in a further study only if (i) The second study exclusively concerns induction therapy; (ii) Consolidation cycle one and two are given according to the accredited study group policy; (iii) No investigational drugs are used post registration for the HCT vs CT in eldery AML study; (iv) Documentation for the HCT vs CT in eldery AML study is not compromised. Second hand data from foreign study is not accepted
Age	60-75 years
Status	Active
start of Recruitment	01.10.2012
Recruiting countries	Germany France The Netherlands Switzerland
Target Sample Size	231

Leader

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Other Registers

ClinicalTrials.govNCT00766779
European Clinical Trials Database - EUDRACT2007-003514-34