European LeukemiaNet
SHORTPROTOCOL
AML Elderly

Scientific Title	Treatment of Elderly Patients (>60 years) with de novo or Secondary Acute Myeloblastic Leukemia or Advanced MDS (RAEB-T): A Study to test the Efficacy of intensive chemotherapy followed by G-CSF and a Feasability Trial of Dose-reduced Allogeneic Transplantation and of Autologous Stem Cell Transplantation
Short Title	AML Elderly
Id KN/ELN	LN_NN_2000_29
Trialgoup	NN
Type of Trial	multicentric
Phase	Phase III
Disease	Myelodysplastic Syndrome(MDS) All subtypes Acute myeloid leukemia(AML) AML all subtypes without FAB M3
Stage of Disease	de novo/non-treated
Aim	- To evaluate the efficacy of intensive induction therapy with Ara-C, Idarubicin and VP16 (IdAV) followed by G-CSF in elderly patients with de novo AML, secondary AML and advanced MDS. - Comparison of the anti-leukemic efficacy of the IdAV regimen followed by G-CSF in de novo AML versus secondary AML and RAEB-T. - Examination of the ability to mobilize sufficient numbers of PBSC for autologous PBSCT after consolidation therapy with dose-reduced FLAG-Ida chemotherapy followed by G-CSF. - Investigation of the feasibility of high dose chemotherapy with autologous PBSC support as late consolidation therapy - To determine the feasibility of allogeneic transplantation with dose-reduced conditioning („mini- / micro- / metakine transplants“) in elderly patients possessing a histocompatible donor - Assessment of minimal residual disease in the course of treatment, including leukemic cell contamination of autologous PBSC grafts.
Outcomes	- Achievement of complete remission (CR) following one or two induction cycles (Primary Outcome) - Overall and disease free survival - Early death rate (during induction) - Percentage of patients with sufficient mobilization of PBSC - Anti-leukemic efficacy, morbidity and mortality of auto-PBSCT - Quality of autologous PBSC (Minimal Residual Disease - MRD) - Anti-leukemic efficacy, morbidity and mortality of dosereduced allo-PBSCT
Inclusion Criteria	- Diagnosis of de-novo AML, FAB M0, 1, 2, 4-7 - Diagnosis of secondary AML after previous chemotherapy and/or radiation - Diagnosis of an advanced MDS, i.e. RAEB-t according to the FAB classification - Extramedullary AML (chloroma, “granulocytic sarcoma”) - Age greater than 60 years (not including 60 years) - ECOG performance status 0, 1, or 2 - Written informed consent
Exclusion Criteria	- Patients with a t(15;17) translocation (these patients will be enrolled in a separate protocol) - Patients with severe cardiac disease (e.g. cardiac failure NYHA III/IV, myocardial infarction within the last 6 months; severe ventricular arrythmias (Lown III or IV)

- Patients with severe complications of the leukemia such as uncontrolled bleeding, pneumonia with hypoxia or shock. In the case that these complications are treated successfully, the patient becomes eligible for the study
- Severe pulmonary disease (diffusion capacity for CO2 of less than 50%)
- Significant renal dysfunction (creatinine clearance < 60/min/min)
- Bilirubin > 2mg% (>34.2 mmol/l)
- Patients with a clinically active second malignancy
- Patients with a psychiatric, addictive, or any disorder wich compromises ability to give truly informed consent for participating in this study
- HIV positivity
- Known refractoriness to platelet transfusion, inability to adequately substitute blood products

Age	>= 60 years
Status	Closed
start of Recruitment	05.01.2000
Recruiting countries	Germany
Target Sample Size	250
Leader	Ottmann, Prof. Dr., Oliver Universitätsklinikum Frankfurt/Main Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern Kai 7 60590 Frankfurt / Main Tel: +49 (0)69 6301 87070 Fax: +49 (0)69 6301 4170 Email: ottmann@em.uni-frankfurt.de
Scientific Contact (WHO)	Ottmann, Prof. Dr., Oliver Universitätsklinikum Frankfurt/Main Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern Kai 7 60590 Frankfurt / Main Tel: +49 (0)69 6301 87070 Fax: +49 (0)69 6301 4170 Email: ottmann@em.uni-frankfurt.de
Contact Person	**Study Physician** Bug, PD Dr. med., Gesine Tel: +49 (0)69 6301 7369 Fax: +49 (0)69 6301 7463 Email: g.bug@em.uni-frankfurt.de **Study Centre** Zander, Caroline Tel: +49 (0)69 6301 4802 Fax: +49 (0)69 6301 7463 Email: c.zander@em.uni-frankfurt.de
Centre of Trial	Universitätsklinikum Frankfurt
Diagnostics	**Cytogenetics** Institut für Humangenetik, Medizinische Hochschule Hannover (MHH)
Other Registers	ClinicalTrials.govNCT00199147 (Primary Register)