KURZPROTOKOLL
AML2003

Öffentlicher Titel	Standard vs. intensivierte Therapiestrategie
Wissenschaftl. Titel	Randomisierter Vergleich zwischen Standard- und intensivierter Therapiestrategie der akuten myeloischen Leukmie des Erwachsenen im Alter von <= 60 Jahren
Kurztitel	AML2003
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, kontrolliert, Investigator Initiated Trial (IIT)
Erkrankung	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
Einschlusskriterien	- de novo or secondary acute myeloid leukemia FAB-subtypes M0-M2 and M4-M7 - de novo or secondary myelodysplastic syndrome WHO-type RAEB-2 - age 16 to 60 years - written informed consent
Ausschlusskriterien	- severe comorbidities - severe, uncontrolled complications of the leukemia - prior therapy for AML/MDS - other simultaneous hematological malignancies - HIV-Infection - known allergies against study medication - pregnancy - missing written informed consent
Alter	16 - 60 Jahre
Fallzahl	600
Sponsor	Universitätsklinikum Dresden
Förderer	Universitätsklinikum Dresden
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT00180102 (primäres Register)
Therapie	AML2003 is a prospective randomized trial, to investigate the value of early allogeneic stem cell transplantation in aplasia after induction therapy for high risk patients with acute myeloid leukemia. A rapid analysis of risk-factors (cytogenetics, FLT3 status, clearance of blasts after first induction) and the donor situation is of utmost importance. For this "fast search" diagnostic, which is accomplished in all enclosed patients, significant resources are provided, to take the load off the participating centers. Furthermore, the relevance of autologous transplantation and the benefit of additional substances within the postremission therapy such as m-AMSA or mitoxantrone will be investigated. There is an up-front randomisation in four therapy arms with two cross-classifying factors of two stages (intensified vs. standard therapy and Ara C vs. Ara C+ mitoxantrone + m-AMSA). Thus, the intergroup treatment schedule of the German Competence Network is integrated into the AML2003 study as a central element and 25% of the patients are treated accordingly. In the intensified therapy arms a risk-adapted and priority-based therapy is implemented, including early allogeneic and consolidating autologous stem cell transplantation, respectively. In addition to the clinical questions , a detailed concomitant research program was initiated for the AML2003 study, to get a better view of the heterogeneity of AML and to open new ways for "custom-made" therapies.