Scientific Title: Allografting as Consolidative Immunotherapy for Older Patients with AML in Complete Remission Using Low Dose TBI, PBSC Infusion And Post-Transplant Immunosuppression With Cyclosporine And Mycophenolate Mofetil

Short Title: SZT Allo SCT with red. conditioning

Id KN/ELN: LN_OSHO_1999_77

Trialgroup: OSHO

Type of Trial: multicentric

Phase: Phase II

Disease: Stem cell transplantation (SCT) AML

Stage of Disease:

Inclusion Criteria:
- Age 61 years and 75 years
- AML as defined by the HOVON/SAKK AML-43 protocol (M0-M2 and M4-M7, FAB classification see Appendix A)
- Refractory anemia with excess of blasts (RAEB) or refractory anemia with excess of blasts in transformation (RAEB-t) with an IPSS score of >1.5 (Appendix B)
- AML in first or later CR
- Have a HLA identical family donor
- Karnofsky score > 70 (see appendix E)
- Written informed consent

Exclusion Criteria:
- AML FAB M3
- Organ dysfunction
- Patients with a creatinine clearance < 50 ml/min
- Cardiac ejection fraction < 40%
- Severe defects in pulmonary function testing (defects are currently categorized as mild, moderate and severe) as defined by the pulmonary consultant, or receiving supplementary continuous oxygen
- Liver function tests: total bilirubin > 2x the upper limit of normal, SGOT and SGPT 4x the upper limit of normal
- Karnofsky score 60 (see appendix E)
- Patients with poorly controlled hypertension
- HIV positivity

Age: 61-75 years

Status: Closed

start of Recruitment: 05.10.1999

Recruiting countries: Germany, France, The Netherlands, Austria

Target Sample Size: 40
**Leader**
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