

Public Title	Comparison of the OSHO Protocol to a Standard Arm Protocol of the German AML Intergroup in Younger Patients With AML
Scientific Title	Randomized phase III study comparing the OSHO arm to the standard intergroup arm Randomized comparison of Mito/FLAG versus Mitoxantron/AraC treatment in patients not in remission after the first induction chemotherapy Randomized comparison between one or two chemotherapy consolidation courses before autologous or allogeneic human stem cell transplantation in adult patients with newly diagnosed AML under the age of 60 years
Short Title	OSHO#61 2002
Id KN/ELN	LN_AMLOSH_2002_22
Trialgoup	OSHO
Type of Trial	multicentric, randomized, prospective
Phase	Phase III
Disease	Acute myeloid leukemia(AML) AML all subtypes without FAB M3
Stage of Disease	de novo/non-treated
Outcomes	<ul style="list-style-type: none">- Event-free survival after therapy (Primary Outcome)- Rate of complete remission ; overall survival, relapse-free interval, leukaemia-free survival after the second induction course
Inclusion Criteria	<ul style="list-style-type: none">- Age ≥ 18 years and ≤ 60 years- Newly diagnosed acute myeloid leukaemia as difined by new WHO classification- Myelodysplastic Syndrome RAEB-T according to FAB-classification (blasts in bone-marrow 20-30%)- de novo AML, secondary AML- patients written informed consent
Exclusion Criteria	<ul style="list-style-type: none">- AML FAB M3 - acute promyelocyte leukemia- Renal failure not AML-related- Hepatic insufficiency not AML-related- Cardiac insufficiency NYHA III + IV- Uncontrolled infection- Pregnancy- Karnofsky-performance-score 10- Secondary malignancies- Severe, decompensated metabolic disorders- HIV- mental impairment with inability to give consent
Age	≤ 60 years
Status	Active
start of Recruitment	04.02.2002
Recruiting countries	Germany Austria
Target Sample Size	300

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
Scientific Contact (WHO)	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
Contact Person	Biometrics Krahl, Dr., Rainer Studiensekretariat Otto, Sandra Tel: +49 (0)341 97-13132 Fax: +49 (0)341 97-13139 Email: sandra.otto@medizin.uni-leipzig.de Homepage: http://haemonko.uniklinikum-leipzig.de
Centre of Trial Diagnostics	Universitätsklinikum Leipzig Morphology Zytomorphologisches Labor der Med.Klinik II, Universität Leipzig Cytogenetics Hämatologisches Labor, Universitätsklinikum Leipzig
Sponsors	Universitätsklinikum Leipzig
Supporters	Bundesministerium für Bildung und Forschung Homepage: www.bmbf.de/ Universitätsklinikum Leipzig
Other Registers	ClinicalTrials.govNCT01414231
Interventions	<ul style="list-style-type: none">- Idarubicin : according to protocol- Cytarabine : according to protocol- Mitoxantrone : according to protocol- Daunorubicin : according to protocol- Cyclophosphamid : according to protocol- Stem cell transplantation : Allogeneic or autologous stem cell transplantation