Public Title	Randomized Phase III Study of Low-Dose Cytarabine and Etoposide with or without All-Trans Retinoic Acid in Older Patients not Eligible for Intensive Chemotherapy with Acute Myeloid Leukemia and NPM1 Mutation
Scientific Title	Randomized Phase III Study of Low-Dose Cytarabine and Etoposide with or without All-Trans Retinoic Acid in Older Patients not Eligible for Intensive Chemotherapy with Acute Myeloid Leukemia and NPM1 Mutation
Short Title	AMLSG 15-10
Id KN/ELN	LN_AMLSGU_2011_399
Trialgoup	AMLSG Ulm
Type of Trial	multicentric, randomized, open-label
Phase	Phase III
Disease	Acute myeloid leukemia(AML) AML all subtypes without FAB M3
Stage of Disease	de novo/non-treated - Therapy concepts for specific genotypes - >= 60 years
Molecular Marker	NPM1
Aim	- Evaluation of overall survival after treatment with low-dose cytarabine and etoposide with or without all-trans retinoic acid (ATRA) in patients with acute myeloid leukemia (AML) and nucleophosmin-1 (NPM1) mutation ineligible for intensive treatment - Evaluation of efficacy based on complete remission (CR) rates, event-free survival (EFS), and cumulative incidences of relapse and deaths in CR
Outcomes	- Gesamtüberleben Overall Survival (OS) - Rate an kompletten Remissionen nach der Induktionstherapie CR) Rates of CR - Kumulative Inzidenzen an Rezidiven (CIR) und Todesfällen in CR (CID) Cumulative incidences of relapse (CIR) and death in CR (CID) - Ereignisfreies Überleben Event-free survival (EFS)
Inclusion Criteria	- Patients with confirmed diagnosis of acute myeloid leukemia according to the World Health Organization (WHO) classification (including de novo AML, t-AML and s-AML) - Presence of NPM1 mutation as assessed in one of the central AMLSG reference laboratories. - Age > 60 years. There is no upper age limit. - No prior chemotherapy for leukemia except hydroxyurea to control hyperleukocytosis if needed for up to 10 days during the diagnostic screening phase. - Signed written informed consent - Men must give their informed consent that they do not father a baby and must use a latex condom during any sexual contact with women of childbearing potential, even if they have undergone a successful vasectomy while on therapy and for 3 month after the last dose of chemotherapy. - WHO performance status 3 - Patients not eligible for intensive chemotherapy according to at least one of the following criteria - - HCT-CI Score >2 (see Appendix F) - - Patient¡¯s decision - - age 75 years
Exclusion Criteria	- All other AML subtypes, in particular those AML with other recurrent genetic changes (according to WHO 2008): - - AML with t(8;21)(q22;q22); RUNX1-RUNX1T1 - - AML with inv(16)(p13.1q22) or t(16;16)(p13.1;q22); CBFB-MYH11 - - AML with t(15;17)(q22;q12); PML-RARA (or other translocations involving RARA)

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- - AML with t(9;11)(p22;q23); MLLT3-MLL (or other translocations involving MLL)
- - AML with t(6;9)(p23;q34); DEK-NUP214
- - AML with inv(3)(q21q26.2) or t(3;3)(q21;q26.2); RPN1-EVI1
- No consent for registration, storage and processing of the individual diseasecharacteristics and course as well as information of the family physician and all other treating physicians about study participation
- Bleeding disorder independent of leukemia
- Uncontrolled infection
- Known positive for HIV, HBV or HCV
- Organ insufficiency (creatinine >1.5x upper normal serum level; bilirubin, AST or ALP >2.5x upper normal serum level, not attributable to AML; heart failure NYHA III/IV; severe obstructive or restrictive ventilation disorder)
- Severe neurological or psychiatric disorder interfering with ability of giving an informed consent
- Patients with a ¡°currently active¡± second malignancy other than non-melanoma skin cancers. Patients are not considered to have a ¡°currently active¡± malignancy if they have completed therapy and are considered by their physician to be at less than 30% risk of relapse within one year.

Age > 60 years

Status No longer recruiting

start of Recruitment 01.01.2011

Recruiting countries Germany

Austria

Target Sample Size 144

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Diagnostics	**Molecular Genetics** Labor für Zytogenetische und Molekulargenetische Diagnostik, Klinik für Innere Med. III, Universitätsklinikum Ulm Institut für Humangenetik, Medizinische Hochschule Hannover (MHH)
	Testmethod Hämatologie, Hämostaseologie, Onkologie Hannover
Sponsors	Ulm University Hospital (Main Sponsor)
Supporters	Bundesministerium für Bildung und Forschung Homepage: www.bmbf.de/
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