KURZPROTOKOLL
AMLSG 15-10

Öffentlicher Titel	Cytarabin und Etoposid mit oder ohne ATRA bei AML mit NPM1-Mutation
Wissenschaftl. Titel	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
Kurztitel	AMLSG 15-10
Studienart	multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
Einschlusskriterien	- 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
Ausschlusskriterien	- 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) - 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 disease-characteristics 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 - 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.

Alter	> 60 Jahre
Molekularer Marker	NPM1
Sponsor	Universität Ulm
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01237808 EudraCT 2010-023409-37