KURZPROTOKOLL
EORTC1301-LG

Öffentlicher Titel	Phase III Chemotherapiestudie bei älteren Patienten mit AML
Wissenschaftl. Titel	10-day decitabine versus conventional chemotherapy (“3+7”) followed by allografting in AML patients 60 years: a randomized phase III study of the EORTC Leukemia Group, CELG, GIMEMA and German MDS Study Group
Kurztitel	EORTC1301-LG
Studienart	Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, kontrolliert, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
Einschlusskriterien	- Age >= 60 years - WHO Performance status: <= 2 - Eligible for standard intensive chemotherapy - Patients of reproductive potential should use adequate birth control measures, as defined by the investigator, during the study treatment period and for at least 3 months after the last study treatment. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1% per year) when used consistently and correctly - Have newly diagnosed AML that is cytopathologically confirmed according to WHO classification (Patients can be diagnosed with AML two months prior to randomization) - De novo or secondary AML is allowed - De novo or secondary AML is allowed WBC is <= 30x10^9/L (measured within 72 hours prior to randomization) - The following laboratory assessments should be done within 7 days prior to randomization and should be within the following range: - -> SGOT (AST) and SGPT (ALT) < 2.5 x the upper limit of normal range (at the laboratory where the analyses were performed) unless considered AML-related - -> Total serum bilirubin level < 2.5 x the upper limit of normal range (at the laboratory where the analyses were performed) unless considered AML-related or due to Gilbert’s syndrome - -> Serum creatinine concentration < 2.5 x the upper limit of normal range (at the laboratory where the analyses were performed) unless considered AML-related - The following treatments for previous MDS or MPN are allowed as long as treatment has stopped one month before inclusion: - -> Growth factors, thrombomimetics, immunosuppression (cyclosporin A, steroids, Antithymocyte globulin etc.), chelation, interferons, anagrelide - -> Lenalidomide, low-dose chemotherapy (low-dose melphalan, hydroxyurea, low-dose cytarabine etc.), tyrosine-kinase inhibitors, histone deacetylase inhibitors (e.g. Valproic acid, panobinostat etc.), mTOR inhibitors, other experimental treatment that is not based on inhibition of DNA methyltransferase - Before patient registration/randomization, written informed consent must be given according to ICH/GCP and national/local regulations
Ausschlusskriterien	- Presence of acute promyelocytic leukaemia (APL, i.e. AML-M3 with t(15;17)(q22;q12); PML-RARA fusion gene and cytogenetic variants) - Presence of blast crisis of chronic myeloid leukaemia - Presence of active central nervous system (CNS) leukaemia

	- No prior treatment for AML (relapsed AML is not allowed), these are any antileukaemic therapy including investigational agents and hypomethylating agents (decitabine, 5-azacytidine). Exception: Treatment with Hydroxyurea (HU) is allowed to control the leukocytosis if given for a maximum of 5 days and is stopped at least two days prior to the start of any of the protocol regimens - No prior treatment for MDS or MPN with: - -> hypomethylating agents (decitabine, 5-azacytidine), OR - -> intensive chemotherapy or transplantation within the last three years - Presence of concomitant severe cardiovascular disease which would make intensive chemotherapy impossible, i.e. arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease, reduced left ventricular function assessed by MUGA scan or echocardiogram. - Presence of concomitant malignancy requiring chemotherapy or any malignancy (except basal and squamous cell carcinoma of the skin) for which the patient received chemotherapy within 6 months prior to randomization - Presence of active uncontrolled infection - Presence of any psychological, familial, sociological or geographical condition in the opinion of the investigator potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial
Alter	60 Jahre und älter
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