KURZPROTOKOLL
AMLSG 12-09

Öffentlicher Titel	Azacitidin, Idarubicin und Etoposid als Induktionstherapie und Erhaltungstherapie mit Azacitidin
Wissenschaftl. Titel	Randomized phase-II trial evaluating induction therapy with idarubicin and etoposide plus sequential or concurrent azacitidine and maintenance therapy with azacitidine
Kurztitel	AMLSG 12-09
Studienart	multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, kontrolliert, mehrarmig
Studienphase	Phase II
Erkrankung	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo

Einschlusskriterien

- Both female and male patients meeting the mentioned inclusion and exclusion criteria will be included in this clinical trial, because the risk to get AML does not depend on a patient's gender. Patients must meet all of the following inclusion criteria to be eligible for enrollment into the study
- Patients with suspected diagnosis of acute myeloid leukemia or related precursor neoplasm, or acute leukemia of ambiguous lineage (classified according to the World Health Organization (WHO) classification)
- Patients considered eligible for intensive chemotherapy
- WHO performance status of <= 2
- Age >= 18 years. There is no upper age limit.
- No prior chemotherapy for leukemia except hydroxyurea to control hyperleukocytosis
- Non-pregnant and non-nursing. Women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test within a sensitivity of at least 25 mIU/mL within 72 hours prior to registration. "Women of childbearing potential" is defined as a sexually active mature woman who has not undergone a hysterectomy or who has had menses at any time in the preceding 24 consecutive months.
- Female patients in the reproductive age and male patients must agree to avoid getting pregnant or to father a child while on therapy and for 3 month after the last dose of chemotherapy.
- Women of child-bearing potential must either commit to continued abstinence from heterosexual intercourse or begin one acceptable method of birth control (IUD, tubal ligation, or partner's vasectomy). Hormonal contraception is an inadequate method of birth control.
- Men 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)
- Signed written informed consent.

Ausschlusskriterien

- The presence of any of the following will exclude a patient from study enrollment:
- AML with other recurrent genetic abnormalities (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
- Performance status WHO >2
- Patients with ejection fraction < 50% by MUGA or ECHO scan within 14 days of day 1
- 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)
- Uncontrolled infection
- 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. - Known positive for HIV - Bleeding disorder independent of leukemia - No consent for registration, storage and processing of the individual disease-characteristics and course as well as information of the family physician and/or other physicians involved in the treatment of the patient about study participation. - No consent for biobanking.
Alter	18 Jahre und älter
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Sponsor	Universität Ulm
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01180322 EudraCT 2009-016142-44