# *KURZPROTOKOLL*
# *SAIL*

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| **Öffentlicher Titel** | Ara-C and Idarubicin in Kompination mit dem SINE-Inhibitor KPT-330 bei refraktärer AML |
| **Wissenschaftl. Titel** | An Investigator-Initiated Study To Evaluate Ara-C and Idarubicin in Combination with the Selective Inhibitor Of Nuclear Export (SINE) Selinexor (KPT-330) in Patients with Relapsed Or Refractory AML |
| **Kurztitel** | SAIL |
| **Studienart** | multizentrisch, prospektiv, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT) |
| **Studienphase** | Phase II |
| **Erkrankung** | Blut: Akute myeloische Leukämie (AML): Rezidiviert/refraktär |
| **Einschlusskriterien** | - To be eligible for this trial, patients must meet the following criteria: 1. Cytological or histological diagnosis of AML with the exception of promyelocytic leukemia (AML M3)<br>- 2. Patients must have relapsed/refractory disease (relapse after stem cell transplantation is permitted) as defined as: patients with <PR after first cycle of induction chemotherapy, or<br>- b. patients with <CR(i) after second cycle of induction chemotherapy, or<br>- c. patients who relapse after conventional chemotherapy or<br>- d. patients who have undergone a single stem cell transplantation and who have relapse of their AML.<br>- 3. Men and women aged >= 18 years and eligible for standard dose of chemotherapy (7+3);<br>- 4. A period of at least 3 weeks needs to have elapsed since last treatment (with the exception of hydroxyurea) before participating in this study. Hydroxyurea induction therapy to reduce peripheral blast counts is permitted prior to initiation of treatment on protocol. Treatment may begin in <3 weeks from last treatment if deemed in the best interest of the patient after discussion with the PI of the study;<br>- 5. ECOG performance status <= 2<br>- 6. Serum biochemical values with the following limits unless considered due to leukemia: creatinine <= 2 mg/dl; total bilirubin <= 2x ULN, unless increase is due to hemolysis or congenital disorder; transaminases (SGPT or SGOT) <= 2.5x ULN<br>- 7. Ability to swallow and retain oral medication<br>- 8. Ability to understand and provide signed informed consent;<br>- 9. Cardiac ejection fraction must be >/=50% (by echocardiography).<br>- 10.Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures. |
| **Ausschlusskriterien** | - Patients with any of the following will not be eligible for participation: 1. Treatment with any investigational agent within four weeks.<br>- 2. Cumulative anthracycline dose (daunorubicin or equivalent) >360 mg/m²<br>- 3. HIV infection<br>- 4. Presence of any medical or psychiatric condition which may limit full compliance with the study, including but not limited to:<br>- 5. Presence of CNS leukemia<br>- 6. Unresolved toxicity from previous anti-cancer therapy or incomplete recovery from surgery.<br>- 7. For patients after SCT as part of prior treatment: a. Necessity of immunosuppressive drugs b. GvHD > grade 1 |

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| | - 8. Any of the following within the 12 months prior to study drug administration: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft, symptomatic congestive heart failure, cerebrovascular accident or transient ischemic attack, pulmonary embolism, deep vein thrombosis, or other thromboembolic event.<br>- 9. Ongoing cardiac dysrhythmias of NCI CTCAE Grade >= 2.<br>- 10.Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or study drug administration, or may interfere with the interpretation of study results, and in the judgment of the investigator would make the patient inappropriate for entry into this study.<br>- 11. Clinically significant bleeding within 1 month |
| **Alter** | 18 Jahre und älter |
| **Fallzahl** | 25 |
| **Sponsor** | GSO Global Clinical Research B.V. |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT02249091<br>EudraCT 2014-000526-37 |
| **Therapie** | ARA-C + Idarubicin+ Selinexor (KPT-330) |