

## **KURZPROTOKOLL MIDOKIT**

<b>Öffentlicher Titel</b>	Midostaurin und Standardchemotherapie bei KIT- oder FLT3-ITD positiver t(8;21) AML
<b>Wissenschaftl. Titel</b>	A single-arm phase II trial to assess the efficacy of midostaurin (PKC412) added to standard primary therapy in patients with newly diagnosed c-KIT or FLT3-ITD mutated t(8;21)AML
<b>Kurztitel</b>	MIDOKIT
<b>Studienart</b>	multizentrisch, prospektiv, offen/unverblindet, einarmig
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
<b>Ziele</b>	<ul style="list-style-type: none"><li>- To compare CR, OS, and CIR rates in the two arms</li><li>- To compare the toxicity profile in the two arms</li><li>- To compare the kinetics of MRD in the two arms</li><li>- To compare the duration of patient hospitalization in the two arms</li><li>- To compare the QoL between the two arms</li><li>- To compare the event free survival rates in the two arms in the whole population</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Signed written informed consent according to IGH/EU/GCP and national local laws</li><li>- Newly diagnosed APL confirmed by the presence of t (15;17) or PML/RAR by RT-PCR or micro speckled PML nuclear distribution in leukemic cells</li><li>- Age <math>\geq 18</math> and <math>&lt; 71</math> years</li><li>- WHO performance status 0-2 included</li><li>- Serum total bilirubin <math>\leq 3.0</math> mg/dl</li><li>- Serum creatinine <math>\leq 3.0</math> mg/dl</li><li>- WBC at diagnosis <math>\leq 10 \times 10^9 /L</math></li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Age <math>&lt; 18</math> and <math>\geq 71</math></li><li>- WBC <math>&gt; 10 \times 10^9 /L</math></li><li>- Active malignancy at time of study entry</li><li>- Lack of diagnostic confirmation at genetic level</li><li>- Significant arrhythmias, EKG abnormalities or neuropathy</li><li>- Cardiac contraindications for intensive chemotherapy (L-EF <math>&lt; 50\%</math>)</li><li>- Uncontrolled, life-threatening infections</li><li>- Severe uncontrolled pulmonary or cardiac disease</li><li>- Women who are either pregnant or breast feeding, or of child-bearing potential, defined as all women physiologically capable of becoming pregnant, UNLESS they meet on eof the following definitions: Amenorrhea, post surgical bilateral oophorectomy with or without hysterectomy Using a highly effective method of birth control (defined as those which result in a failure rate less than 1 % per year) when used consistently an d correctly such as implants, injectables, oral contraceptives, IUDs, sexual abstinence or vasectomized partner</li><li>- Concomitant severe psychiatric disorder</li><li>- HIV positivity</li><li>- Use of other investigational drugs at the time of enrolment or within 30 days before study entry</li></ul>
<b>Alter</b>	18 - 70 Jahre
<b>Molekularer Marker</b>	FLT3 AML-ETO KIT
<b>Fallzahl</b>	1

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MIDOKIT**

**Prüfzentren**

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**Registrierung in anderen  
Studienregistern**

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