



Fondation du Centre  
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

### ZOOM SAKK 30/09 HOVON 102

<b>Indication</b>	<b>Leucémie myéloïde aiguë</b>
<b>Title</b>	Randomized study with a run-in feasibility phase to assess the added value of Clofarabine in combination with standard remission-induction chemotherapy in patients aged 18-65 years with previously untreated acute myeloid leukemia (AML) or myelodysplasia (MDS) (RAEB with IPSS $\geq$ 1.5)
<b>Protocol ID</b>	<b>SAKK 30/09 HOVON 102</b>
<b>Phase</b>	Phase III
<b>Sponsor</b>	Hemato-Oncology Cooperative <b>Hovon</b> Group / <b>SAKK</b> (Swiss Group for Clinical Cancer Research)
<b>Local Principal Investigator</b>	Dr Jean-François Lambert
<b>Primary Objective</b>	<p><b>Part A:</b> To determine the feasibility of Clofarabine when given at three possible dose levels together with standard induction cycles I and II in patients with AML/ RAEB with IPSS<math>\geq</math>1.5 in a prospective comparison to standard induction cycles I and II without Clofarabine.</p> <p><b>Part B:</b> To evaluate the effect of Clofarabine at the selected feasible dose level when combined with remission induction chemotherapy cycles I and II as regards clinical outcome ("event-free survival") in comparison to remission induction cycles I and II with no addition of Clofarabine in a phase III study.</p>
<b>Inclusion/exclusion criteria</b>	<p><b>Inclusion Criteria include the following :</b></p> <ul style="list-style-type: none"> <li>◆ Age 18-65 years, inclusive</li> <li>◆ Subjects with <ul style="list-style-type: none"> <li>- a cytopathologically confirmed diagnosis of AML according WHO classification (excluding acute promyelocytic leukaemia) <b>or</b></li> <li>- a diagnosis of refractory anemia with excess of blasts (RAEB) and IPSS score <math>\geq</math>1.5 <b>or</b></li> <li>- patients with therapy-related AML/RAEB <b>or</b></li> <li>- patients with biphenotypic leukemia (Appendices A1 and A2).</li> </ul> </li> <li>◆ WHO performance status 0, 1 or 2</li> <li>◆ Written informed consent</li> </ul>

**Exclusion Criteria include the following:**

- ◆ Acute promyelocytic leukaemia
- ◆ Previous treatment for AML or RAEB, except hydroxyurea
- ◆ Impaired hepatic or renal function as defined by:
  - ALT and/or AST > 3 x Upper Limit of Normal (ULN),  
or
  - Bilirubin > 3 x ULN, or
  - Serum creatinine > 3 x ULN (after adequate hydration),  
unless these are most likely caused by AML organ  
infiltration,
- ◆ Concurrent severe and/or uncontrolled medical condition  
(e.g. uncontrolled diabetes, infection, hypertension,  
pulmonary disease etcetera),
- ◆ Cardiac dysfunction as defined by:
  - Myocardial infarction within the last 6 months of study  
entry, or
  - Reduced left ventricular function with an ejection  
fraction < 50% as measured by MUGA scan or  
echocardiogram (another method for measuring cardiac  
function is acceptable), or
  - Unstable angina, or
  - Unstable cardiac arrhythmias
- ◆ Pregnant or lactating females
- ◆ Unwilling or not capable to use effective means of birth  
control