

Fondation du Centre Pluridisciplinaire d'Oncologie

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Pluridisciplinaire d'Oncologie

ZOOM APL 2006

Indication	Leucémie promyélocytaire aiguë
Title	A randomized phase III trial assessing the role of arsenic trioxide and/or ATRA during consolidation course in newly diagnosed acute promyelocytic leukemia (APL)
Protocol ID	APL 2006
Phase	Phase III
Sponsor	SAKK en collaboration avec le groupe français Assistance Publique – Hopitaux de Paris
Local Principal Investigator	Dr Jean-François Lambert
Primary Objective	Assessing the role of arsenic trioxide and/or ATRA during consolidation course in newly diagnosed acute promyelocytic leukemia (APL)
Inclusion/exclusion criteria	<p>Inclusion Criteria include the following :</p> <ul style="list-style-type: none">• Diagnosis of APL based on morphological grounds, which will have to be confirmed by the presence of t(15;17) and/or PML-RARA rearrangement with characterization of the bcr subtype (PML-RAR characterization) in a reference laboratory.• Untreated patients.• No contraindication to intensive chemotherapy (especially well documented cardiac contraindication to idarubicin).• In female patients: absence of pregnancy and adequate contraceptive methods (due to teratogenic effects of ATRA in early pregnancy).• Absence of Hypersensitivity to Arsenic derivatives.• No QT interval prolongation or complete atrio-ventricular block.• Written informed consent. <p>Exclusion Criteria include the following:</p> <ul style="list-style-type: none">• Patients already treated.• Patients with contraindication to intensive chemotherapy, especially well documented cardiac contraindication to Idarubicin.• In female patients: pregnancy or absence of adequate contraceptive methods.• QT interval prolongation or complete atrio-ventricular block.

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| | <ul style="list-style-type: none">• Hypersensitivity to Arsenic derivatives. |
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