

A phase 2 prospective multicenter trial endorsed the safety and efficacy of a sequential regimen of clofarabine, cytosine arabinoside and reduced intensity transplantation for primary refractory acute myeloid leukemia




24 adult patients with acute myeloid leukemia



38% Intermediate cytogenetics

62% Poor cytogenetics

Sequential regimen

	days -13 to -9	clofarabine (30 mg/m ² /d) and cytosine arabinoside (1 g/m ² /d)
	days -9 to -6	rest
	days -5 to -2	RIC allo-SCT combining cyclophosphamide (60 mg/kg), intra-venous busulfan (3.2 mg/kg/d) for 2 days and anti-thymocyte globulins (2.5 mg/kg/d) for 2 days
	day 0	graft infusion
	day +120	patients in complete remission received prophylactic donor lymphocyte infusion

75%

patients achieved complete remission



median follow-up of 24.6 months

	1-year	2-years
Kaplan-Meier estimate of overall survival	54%	38%
Kaplan-Meier estimate of leukemia-free survival	46%	29%
Cumulative incidence of non-relapse mortality	8%	12%