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

<table>
<thead>
<tr>
<th></th>
<th>days</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-13 to -9</td>
<td>clofarabine (30 mg/m²/d) and cytosine arabinoside (1 g/m²/d)</td>
</tr>
<tr>
<td></td>
<td>-9 to -6</td>
<td>rest</td>
</tr>
<tr>
<td></td>
<td>-5 to -2</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>graft infusion</td>
</tr>
<tr>
<td></td>
<td>+120</td>
<td>patients in complete remission received prophylactic donor lymphocyte infusion</td>
</tr>
</tbody>
</table>

- 75% patients achieved complete remission
- Median follow-up of 24.6 months

### Kaplan-Meier estimate of overall survival
- 1-year: 54%
- 2-years: 38%

### Kaplan-Meier estimate of leukemia-free survival
- 1-year: 46%
- 2-years: 29%

### Cumulative incidence of non-relapse mortality
- 1-year: 8%
- 2-years: 12%

Mohty et al., Haematologica, 2016