This trial is ongoing to deactivity of SGN-CD33A and enablement of allogeneic SCT. 

Conclusions: These case reports support the anti-leukemic activity of SGN33A (60 mcg/kg). He had ECOG 0, G3 neutropenia, hemodialysis. He had 4 cycles of idarubicin + cytarabine 2013 which was complicated by acute renal failure requiring CR with high-dose cytarabine + idarubicin induction Jul (nucleophosmin cytoplasmic and IDH2 mutations) achieved CR in 83%, but with persistent disease (morphologic or MRD+) by flow or molecular markers in 67%. BM was the graft source in 3 patients (12.5%) and PBSC in 21 (87.5%), non T-cell depleted in all cases. The haploidentical donor was the patient's mother (21%), father (12.5%), siblings (41.5%) or offspring (25%), MAC regimen was BUX3 in 8 (33%) and BUX4 in 16 patients (67%). Median infused CD34+ cells were 4,93x10^6/kg (3,20-8,43). Median neutrophils engraftment was reached at day +16 (13-29) and platelets >20K at day +27 (11-131). Complete chimerism was obtained at a median of 22 days (13-44) in 21 evaluated patients. Cumulative incidence (CI) of non-relapse mortality (NRM) was 21.5% at 1 year. CI of grade II-IV acute GVHD was 45.5% at day +100, and grade III-IV was 9%. CI of chronic GVHD at 1 year was 35%, being extensive in 8%. No differences in acute or chronic GVHD CI were seen when comparing BUX3 against BUX4. After a median follow-up of 15 months (3-31), estimated 18-months event-free survival (EFS) and overall survival (OS) were 63% and 75% respectively. CI of relapse or progression was 19.5%. No significant differences in NRM, EFS, OS and relapse incidence were detected between BUX3 and BUX4. The effect of CR prior to MAC-HAPLO has not been appropriately assessed due to the limited number of events in our series.

Conclusions: IV Busulfan based MAC-HAPLO with PT-CY in the treatment of high risk leukemias and MDS offers good disease control with manageable toxicity, with either BUX3 or BUX4.

**Myeloablative Haploidentical Stem Cell Transplantation (MAC-HAPLO) with Post-Transplant Cyclophosphamide (PT-CY) As GVHD Prophylaxis in High Risk Leukemias/Myelodysplastic Syndromes (MDS)

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**Introduction:** Allogeneic transplantation is the only curative option for patients with high risk leukemias or MDS. Only one third of them have an HLA identical sibling donor and around 60-70% will find an unrelated donor; that’s why haploidentical stem cell transplantation (HAPLO-HSCT) offers a therapeutic option to most of these patients. Myeloablative conditioning (MAC) used to obtain better disease control than reduced intensity conditioning regimens (RIC), but with higher toxicity, rendering long term similar results.

**Patients and Methods:** We retrospectively evaluated the results in patients diagnosed with high risk leukemias or MDS of our MAC-HAPLO regimens (Fludarabine 30 mg/m² x5 days (-6 to -2), Cyclophosphamide14,5 mg/kg x2 days (-6 to -5), IV Busulfan 3,2 mg/kg x 3 days (BUX3) on days -4 to -2, or Fludarabine 40 mg/m² x4 days (-6 to -2) and IV Busulfan 3,2 mg/kg x 4 days (BUX4)) with GVHD prophylaxis based on PT-CY (50 mg/kg on days +3 and +4) and a calcineurin inhibitor plus mycophenolate from day +5, performed in GETH centers.

**Results:** From Feb 2011, 24 MAC-HAPLO have been done in 7 centers. Median age was 37 years (15-65), 58% were males and all were in advanced disease phase or presented high risk features (AML 16/ALL 4/MDS 2/ CMML 1/ CMML 1). Previous HSCT had been employed in 21% (autologous in 1, allogeneic in 4), and in 79% the HAPLO-HSCT was their first transplant. Disease status at HAPLO-HSCT was morphologic CR in 83%, but with persistent disease (morphologic or MRD+) by flow or molecular markers in 67%. BM was the graft source in 3 patients (12.5%) and PBSC in 21 (87.5%), non T-cell depleted in all cases. The haploidentical donor was the patient’s mother (21%), father (12.5%), siblings (41.5%) or offspring (25%), MAC regimen was BUX3 in 8 (33%) and BUX4 in 16 patients (67%). Median infused CD34+ cells were 4,93x10^6/kg (3,20-8,43). Median neutrophils engraftment was reached at day +16 (13-29) and platelets >20K at day +27 (11-131). Complete chimerism was obtained at a median of 22 days (13-44) in 21 evaluated patients. Cumulative incidence (CI) of non-relapse mortality (NRM) was 21.5% at 1 year. CI of grade II-IV acute GVHD was 45.5% at day +100, and grade III-IV was 9%. CI of chronic GVHD at 1 year was 35%, being extensive in 8%. No differences in acute or chronic GVHD CI were seen when comparing BUX3 against BUX4. After a median follow-up of 15 months (3-31), estimated 18-months event-free survival (EFS) and overall survival (OS) were 63% and 75% respectively. CI of relapse or progression was 19.5%. No significant differences in NRM, EFS, OS and relapse incidence were detected between BUX3 and BUX4. The effect of CR prior to MAC-HAPLO has not been appropriately assessed due to the limited number of events in our series.

**Conclusions:** IV Busulfan based MAC-HAPLO with PT-CY in the treatment of high risk leukemias and MDS offers good disease control with manageable toxicity, with either BUX3 or BUX4.