

BACKGROUND: ALL is the most common childhood cancer. The cure rates have improved dramatically over the past decades and are higher than 80% due to collaborative chemotherapy protocols. However, survival is poor for those who relapse and the results for most of the conventional salvage protocols are still unsatisfying, with cure rates inferior to 40%. BLINA, a bi-specific T-cell engager antibody with specificity to both CD19 and CD3, appears to be a promising novel immunotherapy treatment for B-ALL patients.

HYPOTHESIS: the use of BLINA will allow sustained remissions prior to stem-cell transplantation.

METHODS: We describe the clinical course, cytological and immunophenotypical findings of 2 patients with refractory ALL, whom achieved full remission (CCR) (no identified minimal residual disease – MRD) after two weeks of BLINA continuous infusion.

RESULTS: 1st patient: 4 year-old WB initially diagnosed when 2-year old with classical B-cell leukemia. He was treated according to the Pediatric Brazilian ALL protocol (GBTLI 2009), achieving CCR after a classical induction phase with Prednisone/Daunorubicin/Cytarabine/Asparaginase. He underwent a marrow relapse at the end of his maintenance. The immunophenotypical and cytogenetic aspects were unchanged and several salvage protocols were offered while in parallel to the search of an adequate stem-cell donor. He was given even Clofarabine containing schedules, without attaining a sustained remission. BLINA was then given as a last option prior to a satisfactory cord blood transplantation. Treatment plan consisted of 28 days of continuous drug infusion, initial dose of 5 mcg/m²/day/x 7 days, followed by a dose escalation to 15 mcg/m²/day/x 21 days. CCR with no MRD was verified at the 15th and 28th days. Stem cell transplantation was performed afterwards. 2nd patient: 14 year-old girl diagnosed with B-cell ALL and *ABL1* gene amplification. She failed to achieve remission after being treated *as per* COG ALL 2011, being then switched to the BFM 2002 protocol. A transient CCR was achieved. After recurrence several unsuccessful reinduction trial were attempted. She was finally given BLINA (same schedule as above), also achieving CCR at the 15th day, confirmed at 28 day (no MRD). A haploidentical transplant was then performed, the child achieving full donor chimerism and remaining free of disease by day +30 after transplant. Blinatumomab is a novel and promising agent for the treatment of relapsed and refractory ALL. Both patients here presented achieved CCR, with no detectable MRD, after 15 days of exposure to BLINA. Although entire 28-day cycles were given, one can speculate about proceeding with the planned BMT after the initial 2 weeks of treatment, provided a full remission is achieved.