

abstract

Role of Human Granulocyte Colony-Stimulating Factor (rHuG-CSF) in Myelosuppressive Therapy-Induced Febrile Neutropenia in Children with Acute Lymphoblastic Leukaemia: Real World Data from Central India

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Role of Human Granulocyte Colony-Stimulating Factor (rHuG-CSF) in Myelosuppressive Therapy-Induced Febrile Neutropenia in Children with Acute Lymphoblastic Leukaemia: Real World Data from Central India

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Introduction: This study was planned to explore the efficacy of rHuG-CSF in myelosuppressive therapy-induced febrile neutropenia (FN) among children with acute lymphoblastic leukaemia (ALL) due to paucity of evidence from low-middle-income countries (LMICs).

Primary objective was to find out the time to defervescence and time to neutrophil recovery (absolute neutrophil count (ANC) >1000 cells/mm³) in these leukemic children with FN. The secondary objective was to find out the duration of hospitalisation, time to withdrawal of antibiotics and the adverse effects of rHuG-CSF in them.

Methodology: This prospective interventional study was conducted in the State Government Cancer Institute of Central India from January 2022 to August 2024 among hundred children with ALL from 1 to 14-years of age treated with ALL-IC-BFM-2009 chemotherapy. Those children admitted with fever defined as oral temperature $>38.3^{\circ}\text{C}$ unrelated to transfusions along with grade-IV neutropenia (ANC <500 /mm³) were given rHuG-CSF subcutaneously with a dose of 5 mcg/kg/day, for up to 2-weeks or until the ANC reached 1000 cells/mm³.

ANC levels were measured daily and temperature was documented 6-hourly. Primary end points included time to defervescence and time to neutrophil recovery.

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Secondary end points measured were length of hospitalization and time to withdrawal of antibiotics. All clinically significant adverse effects after administering rHuG-CSF were documented.

Results: In this study the most common age group affected was between 5 to 12-years (75%) and 63% were males. Most of the children (n=54) received rHuG-CSF for 3-days and maximum duration of administering rHuG-CSF was 7-days. Mean time for resolution of fever was 4.6 ± 0.89 days and for resolution of neutropenia was 2.2 ± 0.75 days. Mean duration of hospitalization was 12.7 ± 3.17 days and mean duration of IV antibiotics usage was 8.8 ± 2.36 days. The most common adverse effect of rHuG-CSF was bony pain (52%) followed by vomiting (30%) and headache (18%).

Based on the current available evidence and physician experience, the optimum application of rHuG-CSF in myelosuppressive therapy-induced FN among children with ALL in clinical practice is controversial, embarking the need of this study. This study provides the data from LMICs regarding the efficacy of rHuG-CSF in accelerating resolution of fever and recovery of neutropenia. It also exhibited efficacy in terms of duration of hospitalization and IV antibiotic usage in leukemic children with FN. rHuG-CSF was well tolerated in children with bony pains being the commonest adverse effect, similar to the findings by Sasse et al.

Conclusion: We conclude that in our experience rHuG-CSF can be safely administered to children with ALL in the treatment of myelosuppressive therapy-induced FN and is beneficial in ameliorating neutropenia.