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Palonosetron compared with ondansetron in pediatric cancer patients: multicycle analysis of a randomized Phase III study.

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<u>Abstract</u>

AIM: To investigate across multiple cycles the efficacy and safety of palonosetron in the prevention of chemotherapy-induced nausea and vomiting in pediatric cancer patients receiving highly or moderately emetogenic chemotherapy (HEC/MEC).

PATIENTS & METHODS: Patients were randomly assigned to 10, 20 μ g/kg palonosetron or 3 × 150 μ g/kg ondansetron for up to four cycles of HEC/MEC.

RESULTS: In all on-study chemotherapy cycles, complete response rates were higher in patients in the 20 μ g/kg palonosetron group than the ondansetron group. Treatment-emergent adverse events were comparable between the palonosetron 20 μ g/kg and ondansetron groups.

CONCLUSION: Over four cycles of HEC/MEC, 20 μ g/kg palonosetron was an efficacious and safe treatment for the prevention of chemotherapy-induced nausea and vomiting in pediatric cancer patients.