A Real-life use of IV naxitamab for children with relapsed/refractory neuroblastoma

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Abstract

The use of the anti-GD2 antibody naxitamab (Danyelza) is associated with significant adverse effects (AEs) requiring complex supportive care. Israel was the first country outside the USA in which Naxitamab use was approved; however, experience with Naxitamab related toxicity is limited. We report on the safety and feasibility of a simplified administration protocol for naxitamab that will facilitate its use in institutions with no prior participation in a naxitamab clinical study. Methods: Between November 2021 and July 2023, 102 Naxitamab infusions were administered to 9 patients at the Shaare Zedek Medical Center in Jerusalem. Treatment was given as part of a compassionate use protocol or following approval of the Israeli Ministry of Health (February 2022). Patients received standard premedication, including paracetamol, dipyrone, promethazine, saline bolus, and low-dose opiate. IV naxitamab was given over 30 minutes. Ketamine was used as the only analgesic drug used concurrently with the infusion of naxitamab. Results: Pain was controlled in all cases and other AEs were reported in only 20/95 infusions (21%). Grade 3-4 AEs, including hypotension, hypertension or desaturation, occurred in 10/102 infusions (10%). All AEs were transient, occurring in the first two treatment cycles, and no patient stopped naxitamab therapy due to infusion-related AEs. Two additional pediatric oncology centers in Israel have adopted a modified version of this protocol. Conclusion: Single agent ketamine is a safe and effective treatment for naxitamab-infusion-related pain. Its use is feasible in multiple clinical settings. Significant infusion-related AEs after completion of the 3rd treatment cycle are rare.

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