
Intravesical ICIs to reduce toxicity in NMIBC

Immune checkpoint inhibitors (ICIs) might be an effective therapeutic option in patients with non-muscle-invasive bladder cancer (NMIBC) who are unresponsive to treatment with Bacillus Calmette–Guérin (BCG), but are associated with severe adverse events (AEs). In a phase I, dose-escalation trial, local treatment with pembrolizumab (given intravesically) was assessed for the first time in patients with NMIBC with the aim to reduce systemic toxicity. Pembrolizumab was detected in the urine and not in blood, and lymphocyte recruitment was observed, suggesting that immune modulation occurred as early as 2 weeks after treatment. Therapy was well tolerated in most patients, with grade 1–2 AEs observed. Despite some limitations (small number of patients ($n = 9$), trial interruption owing to COVID-19, and dose-limiting toxicity reported in 2 patients), these promising results about safety and tolerability of intravesical pembrolizumab support further investigation of this therapy in large trials.

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Original article: Meghani, K. et al. First-in-human intravesical delivery of pembrolizumab identifies immune activation in bladder cancer unresponsive to bacillus Calmette–Guérin. *Eur. Urol.* <https://doi.org/10.1016/j.eururo.2022.08.004> (2022)