The IND226 study was a phase Ib study to determine the recommended phase II dose of durvalumab + tremelimumab in combination with standard platinum-doublet chemotherapy. Sequential administration of multiple agents increases total chair time adding costs overall and inconvenience for patients. This cohort of the IND.226 study evaluated the safety and tolerability of durvalumab + tremelimumab given either sequentially (SEQ) or concurrently (CON). Methods Patients with advanced solid tumours were enrolled and randomised to either SEQ tremelimumab 75 mg IV over 1 h followed by durvalumab 1500 mg IV over 1 h q4wks on the same day, or CON administration over 1 h. The serum pharmacokinetic profile of SEQ versus CON of durvalumab and tremelimumab administration was also evaluated. Results 14 patients either received SEQ (n = 7pts) or CON (n = 7 pts). There were no infusion related reactions. Drug related adverse events (AEs) were mainly low grade and manageable, and comparable in frequency between SEQ/CON- fatigue (43%/57%), rash (43%/43%), pruritus (43%/29%) and nausea (14%/29%). One patient in each cohort discontinued treatment due to toxicity. The PK profiles of durvalumab and tremelimumab were similar between CON and SEQ, and to historical reference data. Conclusions Concurrent administration of durvalumab and tremelimumab over 1 h is safe with a comparable PK profile to sequential administration.


Online Publication: https://link.springer.com/article/10.1007%2Fs10637-020-00904-7

Brief Summary:
The purpose of this study was to find the highest dose of durvalumab or of durvalumab with tremelimumab that can be tolerated without causing very severe side effects when receiving standard chemotherapy and to see what effects the study drugs has on this type of cancer.

Patients may receive durvalumab alone or in combination with tremelimumab.

For more information please visit the [CCTG IND226 trial page](https://www.ctg.queensu.ca)