A Clinical Trial of Neoadjuvant HIVEC™ (Hyperthermic IntraVESical Chemotherapy ) for Treating Intermediate and High-Risk Non-Muscle Invasive Bladder Cancer.


Abstract:

PURPOSE: To report a pilot/feasibility trial of neoadjuvant Hyperthermic IntraVESical Chemotherapy (HIVEC™) prior to transurethral resection of bladder tumor (TURBT) for nonmuscle invasive bladder cancer (NMIBC).

MATERIALS AND METHODS: A pilot/feasibility clinical trial was performed and 15 subjects with intermediate to high-risk NMIBC received HIVEC prior to TURBT. HIVEC consisting of 8 weekly instillations of intravesical MMC (80 mg in 50 mL) delivered with the novel Combat BRS system at a temperature of 43°C for 60 min. Treatment-related adverse effects were measured and subjects were followed for 2 years for disease recurrence.

RESULTS: A total of 119 HIVEC™ treatments occurred. Grade 1 adverse events consisted of irritative bladder symptoms (33%), bladder spasms (27%), pain (27%), hematuria (20%) and UTI (14%). Grade 2 adverse events were bladder calcification (7%) and reduced bladder capacity (7%). No grade 3 or higher toxicity was observed. At TURBT 8 (53%) subjects were complete responders (pT0) while 7 (47%) were partial responders. With a median follow-up of 29 months, the 3-year cumulative incidence of recurrence was 15%.

CONCLUSIONS: The Combat BRS system achieved target bladder temperatures and delivered HIVEC™ with a favorable side-effect profile. Our pilot trial also provides preliminary evidence of treatment efficacy.