

DTX on PC3 cell growth inhibition and similar results were recorded after transfection of PC3 cells with shCYR61. In conclusion, it is possible to design new molecular rationale-based therapeutic strategies in androgen-independent prostate cancer.

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DOCETAXEL AND ZOLEDRONIC ACID COMBINATION ADMINISTERED IN TWO DIFFERENT SEQUENCES IN HORMONE REFRACTORY PROSTATE CANCER PATIENTS: PHASE I CLINICAL STUDY - ZANTE

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Background: Docetaxel (DTX) is effective in the treatment of hormone-refractory prostate carcinoma patients (HRPC). *In vitro* data suggest that zoledronic acid (ZOL) and DTX have a synergistic effect on the growth inhibition of prostate cancer cells and that such synergism is sequence-dependent. Therefore, prostate cancer is a suitable target for a pharmacological combination between DTX and ZOL. On the basis of these considerations, a phase I trial on the combination of ZOL and DTX was designed in the treatment of HRPC.

Materials: A dose-escalation of DTX was planned in combination with a fixed dose of ZOL (2 mg), both administered every 14 days. The following two different sequences of the two drugs were explored: Sequence A: DTX at day 1 followed by ZOL at day 2. Sequence B: ZOL at day 1 followed by DTX at day 2. The first dose level of DTX was 30 mg/m² with a planned dose escalation of 10 mg/m² for each level until 50 mg/m². Serum cytokines and PBMC were also collected prior and after the different treatments at each cycle.

Results: Up to now, we have enrolled 22 patients. Six patients at third level (Sequence B) were required due a case of vascular toxicity of grade III (deep thrombo-phlebitis). A different pattern of circulating angiogenic factors (interleukin 8 and 12, VEGF, PDGF), cytokines (TNF- α , IFN- γ , interleukin 6 and 4) and gamma/delta T lymphocyte subpopulation was recorded in the two different sequences. The study is still ongoing and further results will be presented at GOIM meeting.

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INTRAVESICAL GEMCITABINE VERSUS MITOMYCIN FOR RECURRENT SUPERFICIAL BLADDER TUMOURS (STAGES PTA AND PT1): A RANDOMIZED PROSPECTIVE STUDY

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Background: Approximately, 30–40% of patients with a superficial bladder cancer treated with Bacille Calmette-Guerin (BCG) or epirubicin do not respond and other 35% of initial responders have a relapse within 5 years. We compare the therapeutic efficacy and toxicity of intravesical instillations of Gemcitabine (GEM) with mitomycin C (MMC) in patients with a recurrent superficial bladder cancer.

Methods: Patients with a history of a recurrent Ta-T1, G1-G2 bladder transitional cell carcinoma, previously treated were enrolled in the study. The patients received a 6-week course of GEM instillations or 4-week course of MMC. In both arms, for the initial responders who remained free of recurrences, maintenance therapy consisted of a 10 monthly treatment during the first year. All patients were followed every 6 months by cystourethroscopy.

Results: A total of 120 patients were enrolled and randomly assigned to either the MMC treatment arm or Gemcitabine treatment arm. The remaining 109 patients (55 in MMC arm and 54 in Gemcitabine arm) were evaluable. The median duration of follow-up was (identical for both groups) 34 months.

Of the 54 patients in the Gemcitabine group 42(78%) remained free of recurrence compared to 37 (67%) of the 55 patients treated with MMC ($p = 0.05$). Among patients with recurrences, 10 in the MMC arm and 6 in the Gemcitabine group had progressive disease by stage: either local urothelial spread, or muscle infiltration, in 5 and 3, respectively. Local toxicity in both treatment groups was acceptable. The incidence of chemical cystitis in MMC arm was statistically different from that in GEM group ($p = 0.012$).

Conclusions: Gemcitabine for its better clinical activity and favourable toxicity profile than MMC, is a logical candidate for intravesical therapy in refractory transitional cell patients. Final results will be presented at 2008 ASCO Meeting.

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HIGH-DOSE CHEMOTHERAPY AS INITIAL SALVAGE TREATMENT IN RELAPSED TESTICULAR CANCER PATIENTS

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Background: In the last few years, high dose chemotherapy (HDCT) with haematopoietic stem cell transplantation (HSCT) has been increasingly investigated as a therapeutic option for early or late intensification in patients with poor prognosis germ cell tumor (GCT) or in pats who relapse or who have a partial response after a first line chemotherapy.

Methods: Eleven patients were treated with three cycles of VeIP (ifosfamide 1200 mg/m², mesna 1200 mg/m², cisplatin 20 mg/m², days 1–5 and vinblastine 0.11 mg/kg, days 1–2) and one course of HDCT: Carbo-PEC (carboplatin 400–550 mg/m²/day on day 1, etoposide 450 mg/m²/day, cyclophosphamide 1600 mg/m²/day and mesna 3600 mg/m² on days 1–4) followed on day 7 by HSCT.