

Intra-arterial and Tumor-Targeted Infusion of Gemcitabine in Patients with Unresectable Pancreatic Cancer

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Aim: A dose escalation study of Gemcitabine for treatment of unresectable pancreatic cancer using a targeted intra-arterial delivery catheter (RenovoCath™).

Methods: The plan is to enroll 20 patients at two centers. Each patient will undergo a four-stage dose escalation of Gemcitabine (up to 1000 mg/m²). Enzyme markers, blood count and constitutional endpoints will be monitored to assess for dose-limiting toxicity. The study will also assess the effect on tumor size by imaging, tumor markers and conversion to resectability.

Results: At the time of this writing, seven patients have received 24 treatments with one patient already completing a treatment dose at 1000 mg/m², five patients receiving up to 500mg/m², and two patients receiving 250 mg/m². There has been no dose limiting toxicity observed so far. The only constitutional symptom has been nausea and vomiting in two patients within four hours of treatment. There has been no evidence of pancreatitis or liver enzyme abnormality as assessed the day after or one and two weeks post-procedure. With localized delivery, we have not seen any systemic effect of Gemcitabine on reduction of absolute neutrophil count up to the most common treatment dose of 500 mg/m² tested so far.

Conclusion: Localized and targeted intra-arterial delivery of Gemcitabine (up to doses of 500 mg/m²) appears safe for the treatment of patients with unresectable pancreatic cancer. Once we complete the study, we can establish if dosing up to 1000 mg/m² can be safely achieved in all patients. Secondly, we will establish the impact on tumor size.