Title

IS INTRA-ARTERIAL WITH TARGETED DELIVERY OF GEMCITABINE SAFE IN TREATMENT OF PATIENTS WITH LOCO-REGIONAL PANCREATIC TUMORS?

Authors

1. Alexander Rosemurgy, MD, Florida Hospital, Tampa, FL (first author)
2. Sharona Ross, MD, Florida Hospital, Tampa, FL
3. Paul Vitulli, MD, Florida Hospital, Tampa, FL
4. Reza Malek, MD, El Camino Hospital, Mountain View, CA
5. Jiali Li, MD, El Camino Hospital, Mountain View, CA
6. Ramtin Agah, MD, El Camino Hospital, Mountain View, CA

Introduction

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

Methods

20 patients at two centers to be enrolled with a four-stage dose escalation of Gemcitabine up to 1000 mg/m2. Enzyme markers, blood count, and constitutional endpoint will be monitored to assess for dose-limiting toxicity. Feasibility and safety of repeated intra-arterial treatment sessions will also be assessed. Secondary end points will be to assess the effect on tumor size by imaging, tumor markers and conversion to resectability.

Results

Fourteen patients have received a combined 53 treatments: three patient completing eight sessions with a maximum treatment dose of 1000 mg/m2, six patients dose escalated to 750 mg/m2, and five patients having received a combined 8 treatments up to 500 mg/m2. There has been one dose-limiting adverse event so far. With local targeted delivery, we have not seen significant reduction of absolute neutrophil count and/or platelets by gemcitabine. Lastly, the first patient who has had completed the eight treatment cycle has shown a 19% tumor reduction.

Conclusion

Localized and targeted intra-arterial delivery of Gemcitabine up to doses of 750 mg/m2 appears safe for the treatment of patients with unresectable pancreatic cancer. With completion of study, we can establish if dosing up to 1000 mg/m2 can be safely achieved in all patients and if repeated intra-arterial treatments are feasible. We will also assess the impact of targeted intra-arterial delivery on tumor size as a secondary goal of the study.