Intraperitoneal aerosolized nanoparticle albumin based paclitaxel (NAB-PTX) for irresectable peritoneal metastases: A first in human phase I study

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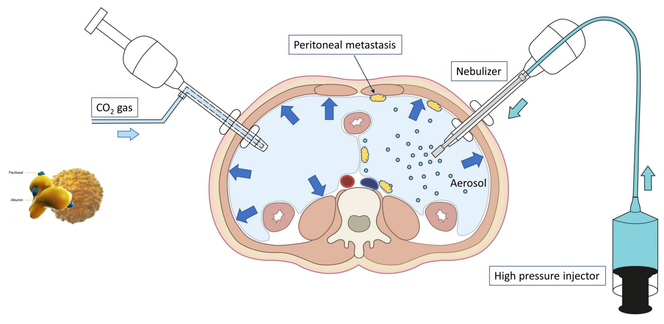
Abstract # 4065

Background

- Pressurized intraperitoneal aerosolized chemotherapy (PIPAC) shows promise in the palliative treatment of peritoneal metastases (PM)
- Preclinical data suggest that intraperitoneal (IP) NAB-PTX (Abraxane®) has superior efficacy in the treatment of PM compared to the standard solvent based paclitaxel (PTX) formulation

Methods:

- First in human phase I dose escalation trial in patients with PM from upper gastrointestinal, breast, or ovarian cancer
- Dose escalated from 35 to 140 mg/m^2 using a Bayesian approach until the maximally tolerated dose (MTD) reached
- Secondary endpoints: morbidity, pharmacokinetics (PK), histological treatment response, EORTC QoL, and overall survival
- Patients underwent three PIPAC procedures with four weeks interval; systemic Tx allowed (exception: paclitaxel)



Laparoscopic intraperitoneal delivery of NAB-paclitaxel as an **aerosol** holds promise for patients with peritoneal metastases

The recommended phase II dose is 112.5 mg/m^2

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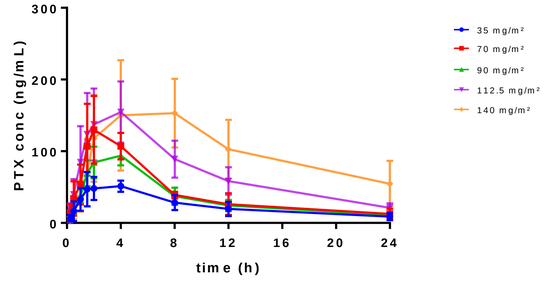
Results

- 23 patients included; 65% combined PIPAC with continued systemic chemotherapy
- No dose limiting toxicity observed; more wound infection or dehiscence at highest dose
- Most frequent toxicities: liver toxicity (grade 1 to 3, 75%) and anemia (grade 1 to 3, 70%)
- Histological response in 35%, stable disease in 35%, progressive disease in 30%,
- PK: T_{max} reached after 2 to 6 h. Median tumor [PTX] suggested accumulation: 9.37 ng/mg, 14.78 ng/mg and 25.75 ng/mg after the 1st, 2nd, and 3rd PIPAC
- EORTC global health, functional, and symptom scores and VAS scores remained stable
- Overall survival after one year 57%



Conclusion

- PIPAC with NAB-PTX is safe, well tolerated, and results in a favorable PK profile and promising anticancer activity. The recommended dose for future phase II trials is 112.5 mg/m^2.

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