TPS4210 **Poster Session**

A phase II study of perioperative intraperitoneal paclitaxel in patients with gastric adenocarcinoma and carcinomatosis or positive cytology.

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Background: Over the last 2 decades, intraperitoneal chemotherapy has been found to have activity for select subgroups of patients with carcinomatosis from colon, ovarian, appendiceal, and recently, gastric origins. However, there is little data to support an aggressive surgical approach of cytoreduction (debulking) and intraperitoneal therapy for patients with gastric cancer and positive cytology or carcinomatosis. Recently, the DRAGON-01 randomized trial reported improvement in outcomes for the addition of intraperitoneal paclitaxel as part of a bidirectional approach with systemic paclitaxel and S-1 for patients with gastric cancer and peritoneal metastases. However, there are few studies supporting intraperitoneal paclitaxel in Western populations. As systemic therapy is improving with concomitant targeted and immunotherapy, intraperitoneal therapy may be best utilized in Western populations after standard of care systemic therapy. Therefore, the purpose of this clinical trial is to determine the efficacy and safety of perioperative intraperitoneal paclitaxel in patients with stage IV gastric cancer limited to the peritoneum after treatment with systemic chemotherapy. **Methods:** Patients with gastric and gastroesophageal adenocarcinoma and positive peritoneal cytology or carcinomatosis that have completed treatment with systemic chemotherapy are offered participation in the study. Patients with metastatic disease not limited to the peritoneum are excluded. Type and duration of systemic chemotherapy is left to the discretion of the treating medical oncologist. Immunotherapy or Her2-directed therapy may continue during the trial. We have recently completed a Phase I clinical trial demonstrating doses of up to 100 mg/m^2 were safe (NCT04220827; PMID: 39287936). Therefore, 100 mg/m^2 is administered intraperitoneal every 2 weeks for three treatments before and after gastrectomy. We also modified the trial to allow for the inclusion of heated intraperitoneal chemotherapy during gastrectomy. The primary outcome is overall survival from the date of diagnosis of stage IV disease, with secondary outcomes of safety. After completion of study–related treatment, subjects will be followed until recurrence and/or death for up to three years. Sixteen of planned 30 patients have been enrolled (NCT05977998). Clinical trial information: NCT05977998. Research Sponsor: None.