TPS5624 **Poster Session**

Rationale and study design of the KOV-HIPEC-04: A phase III randomized controlled trial in primary stage three and four ovarian cancer after interval cytoreductive surgery (FOCUS).

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Background: The addition of hyperthermic intraperitoneal chemotherapy (HIPEC) during interval cytoreductive surgery increases progression-free and overall survival for patients with stage III ovarian cancer in two randomized controlled trials (OV-HIPEC-01 and KOV-HIPEC-01). This trial aims to identify the survival benefit of HIPEC in stage III & IV ovarian cancer in the era of maintenance therapy of bevacizumab and/or PARP inhibitors. **Methods:** Ovarian cancer patients will be randomized at the time of interval cytoreductive surgery with achieving complete cytoreduction or cytoreduction with no more than 2.5mm size of residual disease to receive HIPEC (41.5 cisplatin 75mg/m^2, 90 minutes) or not (Control arm). After recovery from surgery, patients will receive postoperative platinum-based adjuvant chemotherapy followed by maintenance therapy with PARP inhibitor or bevacizumab. The primary objective of the trial is to evaluate OS in two groups. Secondary objectives are PFS, cancer-specific survival, time to first subsequent therapy (TFST), safety, CA-125 KELIM, and quality of life. Assuming that the enrollment period is 5 years and the follow-up period is 3 years, the total number of events required is 263. Based on the log-rank test, the total number of subjects required to prove HR 0.67 with a two-sided alpha of 0.05 and 90% power is 494. Considering 5% drop-out, 520 patients are finally studied. **Results:** The first patient was randomized on June 06, 2023. Until Jan. 26, 2025, 279 (53%) patients are randomized. There are no available results at the time of submission. **Conclusions:** The role of HIPEC during interval cytoreductive surgery will be discovered in stage III & IV ovarian cancer with this randomized trial (KOV-04, FOCUS) in the era of maintenance therapy of bevacizumab and/or PARP inhibitors for the first time. Clinical trial information: NCT05827523. Research Sponsor: National Cancer Center Korea (NCC2110790, NCC2110770).