

Rationale and study design of the KOV-HIPEC-02R (RECOVER): A randomized, multicenter, open-label phase III trial of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy in platinum-resistant recurrent ovarian cancer.

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Background: Hyperthermic intraperitoneal chemotherapy (HIPEC) administered during interval cytoreductive surgery following neoadjuvant chemotherapy has shown to increase progression-free survival (PFS) and overall survival (OS) rates, as indicated by the OV-HIPEC-01 and KOV-HIPEC-01 trials. A recent meta-analysis (Kim SI, Kim JH, et al., GO 2023) demonstrated a survival benefit associated with HIPEC, particularly after recent exposure of chemotherapy. Moreover, in ovarian cancer, HIPEC is suggested to be effective in overcoming chemotherapy resistance. **Methods:** This trial (KOV-02R, RECOVER) is a multicenter, open-label, 1:1 randomized, phase III trial that will enroll 140 patients with platinum-resistant recurrent epithelial ovarian cancer (NCT05316181). After cytoreductive surgery, patients undergo the HIPEC procedure at 41.5°C, with doxorubicin at 35mg/m² and mitomycin at 15mg/m². Enrolled patients receive non-platinum compound systemic chemotherapy until disease progression. The primary objective is to evaluate progression-free survival between the HIPEC group and the control group. Secondary objectives include overall survival, cancer-specific survival, and safety and quality of life. Considering a 5-year enrollment period, 2-year follow-up, and a statistical power of 80%, 140 patients are needed, accounting for a 10% dropout rate. As of January 10, 2025, 115 patients (82.1%) have been randomized. Clinical trial information: NCT05316181. Research Sponsor: None.