

Introduction The addition of hyperthermic intraperitoneal chemotherapy (HIPEC) during interval cytoreductive surgery increases progression-free and overall survival for patients with advanced-stage epithelial ovarian cancer in two randomized controlled trials (OV-HIPEC-01 and KOV-HIPEC-01). The aim of this trial is to identify the survival benefit of HIPEC in advanced ovarian cancer in the era of maintenance therapy of bevacizumab and/or PARP inhibitor.

Methods The KOV-HIPEC-04 is a multicenter, 1:1 randomized, phase III trial that will enroll 520 patients with primary epithelial ovarian cancer who completed neoadjuvant chemotherapy. Patients will be randomized at the time of interval cytoreductive surgery with achieving complete cytoreduction or cytoreduction with no more than 2.5 mm depth of residual disease to receive HIPEC (experimental arm, 41.0–42.0°C cisplatin 75 mg/m², 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 endpoint is to evaluate overall survival (OS); secondary objectives are progression-free survival (PFS), cancer-specific survival, time to first subsequent therapy, safety, 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. 520 patients are finally studied, considering 5% drop-out. ClinicalTrials.gov (NCT05827523)

Current Trial Status Not yet Recruiting

TP018/#822

A RANDOMIZED, MULTICENTER, OPEN-LABEL PHASE III TRIAL OF HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-RESISTANT RECURRENT OVARIAN CANCER

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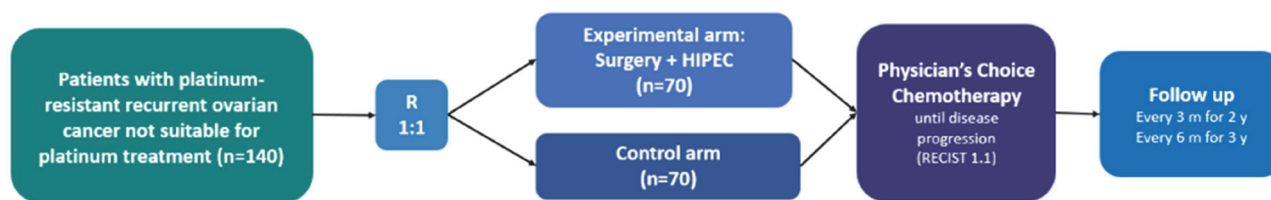
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Introduction Recent randomized trials (OV-HIPEC-01 and KOV-HIPEC-01) and meta-analyses reveal survival benefits of

Randomized Phase III Trial of HIPEC in Platinum-Resistant Recurrent Ovarian Cancer (KOV-HIPEC-02)

ClinicalTrials.gov (NCT05316181)

Primary endpoint: Progression-free survival (PFS)



Stratification factors

1. Histology (HGSOC vs non-HGSOC)
2. Number of prior lines of chemotherapy (≤ 1 line vs ≥ 2 lines)

HIPEC regimen

- Doxorubicin 35mg/m² + Mitomycin C 15mg/m²
- 90 minutes, 41.5 °C (range, 41–42°C)

Abstract TP018/#822 Figure 1

HIPEC after recent exposure of systemic chemotherapy exposure in ovarian cancer.

Methods This trial (KOV-HIPEC-02) is a multicenter, open-label, 1:1 randomized, phase III trial that will enroll 140 patients in platinum-resistant recurrent epithelial ovarian cancer. The trial is registered on ClinicalTrials.gov (NCT05316181). The experimental arm will receive HIPEC (41.0–42.0°C, doxorubicin 35 mg/m² and mitomycin 15 mg/m², 90 min) followed by physician's choice chemotherapy, and the control arm will receive physician's choice chemotherapy without HIPEC until disease progression or unacceptable toxicities. The primary objective of the trial is to evaluate progression-free survival (PFS). Secondary objectives are overall survival (OS), cancer-specific survival, safety, and quality of life. Assuming that the enrollment period is 3 years and the follow-up period is 2 years, the total number of events required is 121. Based on the log-rank test, the total number of subjects required to prove HR 0.6 with a two-sided alpha 0.05 and 80% power is 126. 140 patients are finally studied considering 10% drop-out.

Current Trial Status Active Recruiting

TP019/#1387

ROSELLA (GOG-3073, ENGOT-OV72/MITO): A PHASE 3 STUDY OF RELACORILANT + NAB-PACLITAXEL VS. NAB-PACLITAXEL IN PLATINUM-RESISTANT OVARIAN CANCER

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Introduction Single-agent chemotherapies are commonly used in platinum-resistant ovarian cancer (OC), but outcomes are generally poor. Cortisol, which binds to the glucocorticoid receptor (GR), can suppress apoptotic pathways used by chemotherapy. The selective GR modulator relacorilant may reverse cortisol's anti-apoptotic effects to enhance chemotherapy efficacy. In a phase 2 study in patients with recurrent, platinum-refractory/resistant OC (NCT03776812), intermittently dosed relacorilant + nab-paclitaxel showed clinically meaningful improvement in progression-free survival (PFS), duration of response (DoR), and overall survival (OS) without increased side effect burden vs. nab-paclitaxel monotherapy.

The ROSELLA study aims to confirm these findings in a larger patient population.

Methods ROSELLA (NCT05257408) is a randomized, phase 3, 2-arm, open-label study of relacorilant + nab-paclitaxel vs. nab-paclitaxel monotherapy. Approximately 360 women with platinum-resistant ovarian, primary peritoneal, or fallopian tube cancer who have received 1–3 prior systemic anticancer therapies, including prior bevacizumab, and ≥1 platinum-based therapy are being enrolled. Patients with primary platinum-refractory disease are excluded. Patients are being randomized 1:1 to relacorilant (150 mg the day before, of, and after nab-paclitaxel) + nab-paclitaxel (80 mg/m²) or nab-paclitaxel monotherapy (100 mg/m²); stratified by prior lines of therapy (1 vs >1) and region of world (North America vs. Europe vs. rest of world). Nab-paclitaxel is administered on days 1, 8, and 15 of each 28-day cycle. The primary endpoint is PFS by blinded independent central review. Key secondary and exploratory endpoints include OS, PFS by investigator assessment, objective response rate, best overall response, DoR, safety, pharmacokinetics, pharmacodynamics, patient-reported outcomes, and quality of life.

Current Trial Status Currently enrolling

TP020/#1513

FIRST-IN-HUMAN PHASE 1/2 STUDY OF UBAMATAMAB, A MUC16XCD3 BISPECIFIC ANTIBODY, ADMINISTERED ALONE OR IN COMBINATION WITH CEMIPIMAB IN PATIENTS WITH RECURRENT OVARIAN CANCER

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Introduction Ubatamab (REGN4018) is a MUC16xCD3 bispecific antibody that promotes T cell-mediated cytotoxicity by facilitating contact between cancer cells and T cells. In a Phase 1 study (NCT03564340) in patients with recurrent ovarian cancer (OC), ubamatamab monotherapy demonstrated an acceptable safety profile and durable clinical activity at doses of 20 mg to 800 mg IV weekly (by RECIST and CA-125 response rates), and linear pharmacokinetics up to 800 mg IV weekly.

Methods In Phase 2, up to 150 patients with advanced platinum-resistant OC and elevated serum CA-125 will be randomized 1:1:1 to IV Q3W treatment: ubamatamab 250 mg; ubamatamab 800 mg; or ubamatamab 250 mg plus cemiplimab 350 mg (figure 1). All treatment arms will include weekly step-up dosing of ubamatamab (1 mg week 1, 20 mg week 2, and full dose weeks 3 and 4) to limit risk of