TP016/#1542 A MULTICENTER STUDY OF NIRAPARIB AS MAINTENANCE THERAPY IN BRCA WILD-TYPE, NEWLY DIAGNOSED ADVANCED OVARIAN CANCER (POLO TRIAL)

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Introduction Poly(adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitors have revolutionized the management of ovarian cancer. However, the optimal treatment of BRCA wild-type patients with advanced ovarian cancer remains controversial. The POLO trial aims to investigate the efficacy of niraparib maintenance therapy in patients with BRCA wild-type, newly diagnosed, low-risk advanced ovarian cancer.

Methods The POLO is a multi-center, investigator-initiated, single-arm, phase IV trial of patients with FIGO stage III-IV high-grade serous or endometrioid ovarian cancer. This study includes patients having both germline and somatic wild-type BRCA1/2 genes, no visible residual tumor after primary cytoreductive surgery, and responses to the postoperative platinum-based combination chemotherapy. Patients who received neoadjuvant chemotherapy are excluded. All enrolled patients are treated with niraparib maintenance therapy for three years or until disease progression, unacceptable toxicity, or withdrawal of patient consent. The primary endpoint is 12-month progression-free survival (PFS) rate. The secondary endpoints are overall survival, PFS, time to first subsequent treatment, time to second progression, time to second subsequent treatment, and safety. All patients should provide tumor slides obtained during cytoreductive surgery for a prospective examination of somatic homologous recombination deficiency and homologous recombination repair gene alterations. Pre- and post-niraparib blood samples will be collected for circulating cell-free DNA analyses. Molecular biomarkers that may indicate clinical response to niraparib will be identified. In total, 102 patients will be recruited from six sites. An interim analysis is planned after recruitment of 68 participants.

Current Trial Status Accrual is expected to be completed in December 2023, followed by the presentation of results in 2025.

TP017/#812 A PHASE III RANDOMIZED CONTROLLED TRIAL IN PRIMARY STAGE THREE AND FOUR OVARIAN CANCER AFTER INTERVAL CYTOREDUCTIVE SURGERY (FOCUS/KOV-HIPEC-04)

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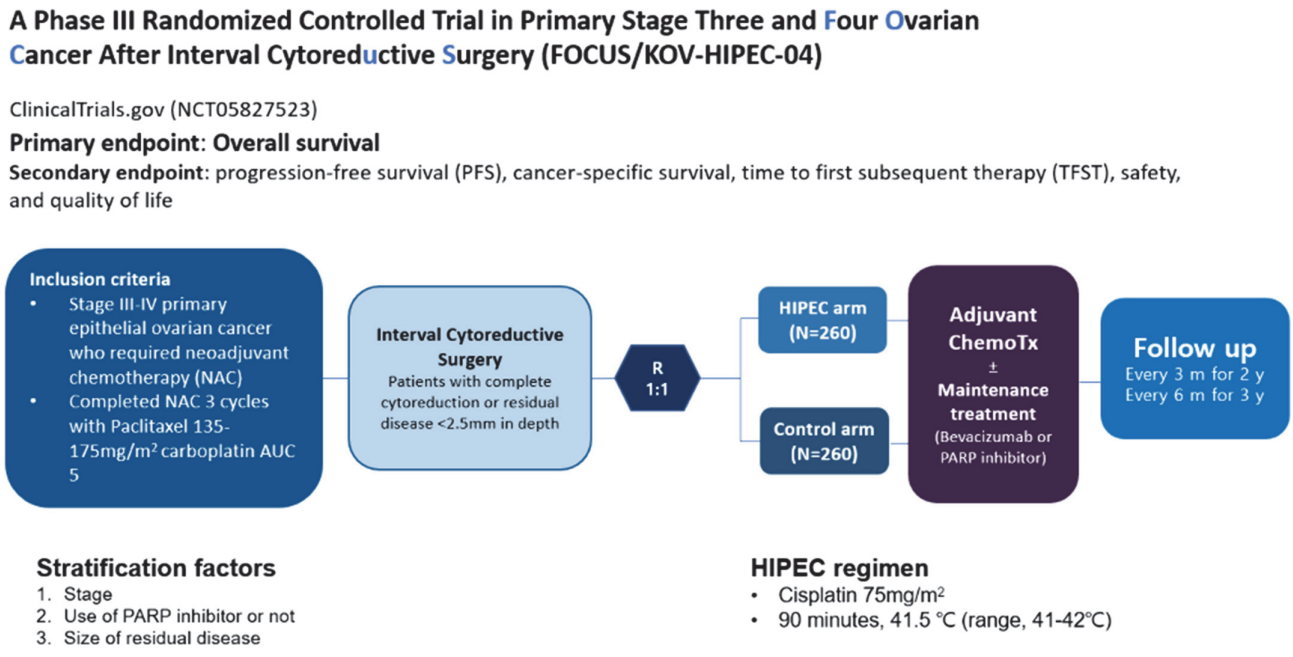

Abstract TP017/#812 Figure 1

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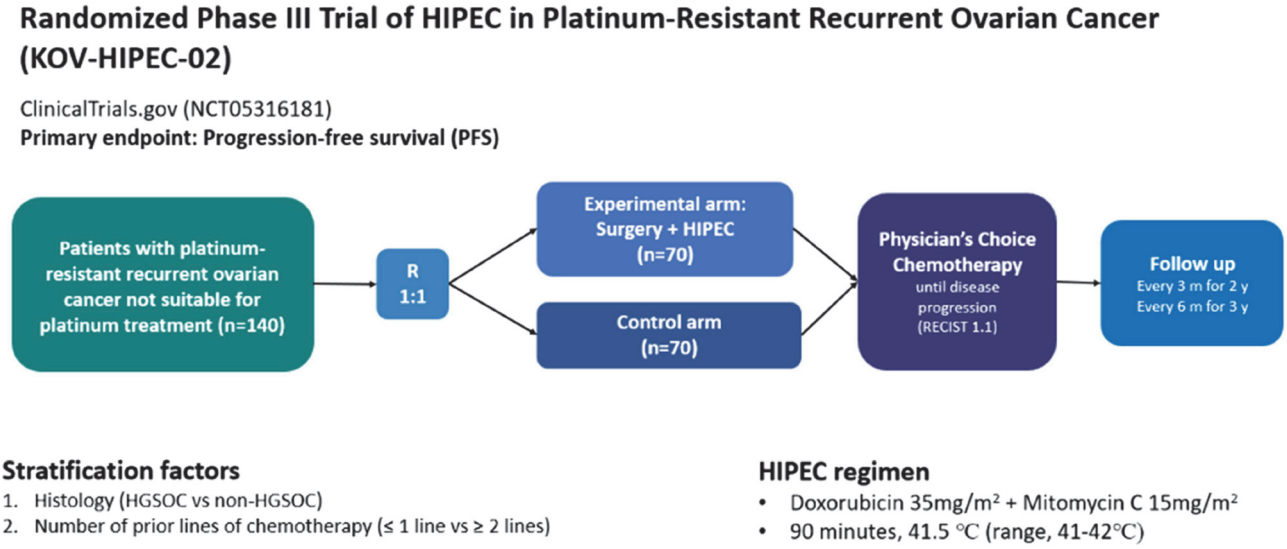
Introduction Recent randomized trials (OV-HIPEC-01 and KOV-HIPEC-01) and meta-analyses reveal survival benefits of



Abstract TP018/#822 Figure 1