monotherapy. Women with platinum-resistant ovarian, primary peritoneal, or fallopian tube cancer who have received 1–3 lines of prior systemic anticancer therapy, including prior bevacizumab, and at least 1 line of platinum-based therapy are being enrolled. Patients with primary platinum-refractory disease are excluded from the trial. Approximately 360 patients are being randomised: 1:1 to relacorilant (150 mg the day before, of, and after nab-paclitaxel infusion) + nab-paclitaxel (80 mg/m²<sup>2</sup>) or nab-paclitaxel monotherapy (100 mg/m²<sup>2</sup>). Nab-paclitaxel is administered on days 1, 8, and 15 of each 28-day cycle. Stratification factors are prior lines of therapy (1 vs >1) and region of world (North America vs. Europe vs. rest of world).

**Results** The primary endpoint is PFS assessed by blinded independent central review. Key secondary endpoints include OS, progression-free survival (PFS), and safety.

**Conclusion**

Frailty is an underdiagnosed multidimensional age-related syndrome. Preoperative frailty assessment is recommended in the guidelines for cancer patients. This study aims to investigate the impact of a standardized, two-step, multidisciplinary evaluation of frailty on complications and prognosis in women with gynecological malignancies, surgically treated.

**Methodology**

In this prospective clinical trial, women with all gynecological malignancies regardless of the previous treatments or the histological type who underwent surgery at the University Medical Centre Mainz from 02/2023 will be consecutively included. All participants undergo the two-step frailty assessment with selected screening tools (Screening I +II) and peripheral blood results and a comprehensive geriatric assessment (CGA).

The main outcome measures will be the relationship between perioperative laboratory results, intraoperative surgical parameters and the incidence of immediate postoperative in-hospital complications and the oncological prognosis with the preoperatively evaluated frailty-status.

**Results**

This is an ongoing trial. So far, 133 patients were recruited for the study: 45 ovarian cancer (33.6%), 40 endometrial cancer (29.9%), cervical cancer 7 (5.2%), 31 vulvar and vaginal cancer (23.3%), as well as 10 others (7.5%).
Abstract #222 Figure 1

Conclusion Frailty is a multidimensional, difficult quantifiable complex. To ensure a possible operationalization, we developed the two-step frailty assessment. This two-step frailty assessment identifies a significant proportion of non-frail patients and women who received optimization of their global health status to realize the standard operation.

Disclosures The authors declare no relevant conflict of interests.

AGO-OVAR 28/ENGOT-OV57: NINAPARIB VS NINAPARIB IN COMBINATION WITH BEVACIZUMAB IN PATIENTS WITH CARBOPLATIN-TAXANE BASED CHEMOTHERAPY IN ADVANCED OVARIAN CANCER (A MULTICENTRE RANDOMISED PHASE III TRIAL)

1Florian Heitz*, 2Edgar Petru, 3Stéphanie Henry, 4Alexander Reuss, 5David Cibula, 6Lydia Gaba, 7Nicoletta Colombo, 8Sandra Polleis, 1Philipp Harter. 1AGO Study Group and Ev. Kliniken Essen-Mitte, Essen, Germany; 2AGO-Austria and Department of Obstetrics and Gynecology, Medical University of Graz, Graz, Austria; 3BGOG and CHU UCL Namur Site Sainte Elisabeth, Namur, Belgium; 4AGO and KKS Marburg, Marburg, Germany; 5CEEGOG and Department of Obstetrics and Gynecology, General University Hospital in Prague, First Medical Faculty of the Charles University, Prague, Czech Republic; 6GEICO and Medical Oncology, Gynecological Cancer Unit, Hospital Clinic de Barcelona, Barcelona, Spain; 7MANGO and IEO, European Institute of Oncology, IRCCS, Milan and University of Milano-Bicocca, Milan, Italy; 8AGO Study Group, Wiesbaden, Germany

10.1136/ijgc-2023-ESGO.875

Introduction/Background Standard of care chemotherapy in patients (pts) with advanced ovarian cancer (AOC) is the combination of carboplatin and paclitaxel (C/P). Data from the PRIMA trial has shown a significant benefit in pts by the addition of a maintenance treatment (MT) with niraparib irrespective of BRCA or HRD-status in high-grade AOC. The PAOLA-1 trial evaluated MT in pts with AOC with the combination of olaparib and bevacizumab and has also shown a significant benefit compared to bevacizumab monotherapy. However, the role/benefit of bevacizumab in addition to PARP-inhibitor (PARPi) in MT is unclear. Therefore, we investigate, if the treatment strategy of carboplatin/paclitaxel/bevacizumab/PARPi is superior to the treatment of carboplatin/paclitaxel/PARPi in a population regardless of biomarker status.

Methodology AGO-OVAR 28/ENGOT-ov57 (NCT05009082; EudraCT-Number: 2021–001271-16) is a multicenter, randomized, prospective phase III trial. The trial population is composed of adult pts with newly diagnosed, high-grade epithelial AOC, primary peritoneal cancer or fallopian tube cancer FIGO III/IV (except FIGO IIIA2 without nodal involvement). All pts should have completed cycle1 of chemotherapy (C/P) as part of Study-Run-In-Period. Prior to day1 of cycle2, 970 pts with a valid central tumor BRCA (tBRCA) test result will be randomized 1:1 into either Arm1 and will receive 5 additional cycles of C/P q21d followed by niraparib for up to 3 years; or into Arm2 where pts will receive 5 additional cycles of C/P plus bevacizumab q21d followed by bevacizumab q21d (for up to 1 year) and niraparib for up to 3 years. Patients who are scheduled for neoadjuvant chemotherapy and interval debulking surgery can also be enrolled. The primary objective is progression-free-survival (PFS). Secondary objectives include but are not limited to: PFS according to tBRCA-status, overall survival, PFS2, safety/tolerability, and quality of life. The trial is currently recruiting, the first patient was randomized in October 2022.

Results Trial-In-Progress

Conclusion Trial-In-Progress

Disclosures Arbeitsgemeinschaft Gynäkologische Onkologie (AGO) Study Group is the sponsor of the trial. Financial support and drug supply by GSK.

Author Disclosure Information F. HEITZ: Honoraria or consultation fees (AstraZeneca, GSK, Roche, Tesaro, MSD); E. PETRU: Honorary for lectures (AGEA, Amgen, Astra Zeneca, Angelini, Eisai, Eli Lilly, Glaxo Smith Kline, MSD, Novartis, Pharma Mar, Pfizer, Roche, Seagen, GILEAD, Pierre Fabre), Honorary for advisory boards (Amgen, Astra Zeneca, Angelini, Eisai, Eli Lilly, Glaxo Smith Kline, MSD, Novartis, Pharma Mar, Pfizer, Roche, Clovis, Daiichi Sankyo, Seagen, GILEAD, Pierre Fabre), Honorary - Institution (Amgen, Astra Zeneca, Angelini, Eli Lilly, Glaxo Smith Kline, Novartis, Pharma Mar, Pfizer, Roche, TESARO, Pierre Fabre), Travel expenses (AGEA, Amgen, Astra Zeneca, Glaxo Smith Kline, Pharma Mar, Pfizer, Roche, Pierre Fabre); S. HENERY: None; A. REUSS: None; D. CIBULA: None; L. GABA: Honoraria or consultation fees (GSK, MSD, AstraZeneca, PharmaMar, Clovis Oncology), Participation in a company sponsored speaker’s bureau (GSK, MSD, AstraZeneca, PharmaMar, Clovis Oncology), Attending meetings or traveling (GSK, MSD, AstraZeneca, PharmaMar, Clovis Oncology); N. COLOMBO: Consultant/Advisor (Roche, PharmaMar, AstraZeneca, Clovis Oncology, MSD, GSK, Tesaro, Pfizer, BIOCAD, Immunogen, Mersana, Eisai, Oncxerna, Nuvation Bio), Promotional Speaker (AstraZeneca, Tesaro, Novartis, Clovis Oncology, MSD, GSK, Eisai), Investigator/Researcher (AstraZeneca, PharmaMar, Roche), Non-financial interests (Steering Committee Member for ESMO Clinical Guidelines, Chair Scientific Committee ACTO onlus); S. POLLEIS: None; P. HARTER: Grants/Research supports (AstraZeneca, Roche, GSK, Genmab, Immunogen, Seagen, Clovis Oncology, Novartis), Honoraria or consultation fees (Amgen, AstraZeneca, Clovis Oncology, Eisai, Exscientia, GSK, Immunogen, Mersana, Miltenyi, MSD, Roche, Sotio, Stryker)