TPS5626 Poster Session

SALVOVAR: A pragmatic randomized phase III trial comparing the salvage weekly dose-dense regimen to the standard 3-weekly regimen in patients with poor prognostic ovarian cancers (GINECO-OV130b; ENGOT-ov78).

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Background: The patients with an advanced epithelial ovarian cancer (EOC) treated with a neo-adjuvant platinum-based chemotherapy who are not amenable to a complete interval debulking surgery (IDS) due to a poorly chemosensitive disease (CA-125 KELIM score <1.0) have a particular poor prognosis (~20% overall survival at 5 years). Several studies suggested that these patients may have a benefit from a chemotherapy densification with the weekly dose-dense carboplatin-paclitaxel regimen. **Methods:** SALVOVAR trial (NCT06476184) is an academic pragmatic open-label multicentre international randomized phase III trial, including stage III-IV high-grade EOC patients who present 2 poor prognostic features after 3-4 cycles of standard neo-adjuvant chemotherapy with carboplatin-paclitaxel administered every 3 weeks: 1) an unfavorable standardized KELIM score <1.0; and 2) a disease considered to be not amenable to a complete IDS. The enrolled patients are randomly allocated (ratio 1:1) to an experimental arm (weekly dose-dense regimen: carboplatin AUC5 and paclitaxel 80 mg/m^2 on day1, day8, and day15, with 3 week cycles) or a control arm (continuation of the standard regimen given every 3 weeks) for 3 cycles. Bevacizumab will be added at investigator discretion. The stratification factors are: Planned administration of bevacizumab (yes, vs no); BRCA mutation (yes, vs no/unknown); and KELIM score strate (moderately unfavorable ≥0.7, vs very unfavorable <0.7). The objective is to show the superiority of the experimental arm with 2 co-primary endpoints: 1) percentage of patients achieving late complete cytoreductive surgery after chemotherapy densification (15% increase), and of overall survival (Hazard-ratio, 0.61). 250 patients will be randomized. The secondary endpoints include overall response rate, progression-free survival, percentage of patients receiving PARP inhibitor and safety. Social human sciences are planned with assessment of the patient/physician perceptions in the shared-decision-making; quality-of-life/patient-reported-outcomes; medico-economic investigation, along with surgical definition of standardized criteria for non-resectability, and inventory of BRCA/homologous-recombination assays used in real-life. The trial is activated in France and Japan. It will be open in United Kingdom, The Netherlands, Italy, Czech Republic, Slovenia, Hungary, Slovakia, and Israel. The recruitment started in July 2024. On January 15 2024, 62 patients had been pre-screened and 18 patients had been randomized. SALVOVAR trial is funded by a European Union HORIZON-MISS-CANCER-2022-01 research program, sponsored by ARCAGY-GINECO (France), and coordinated by Lyon University Hospital (HCL, France). Clinical trial information: NCT06476184. Research Sponsor: None.