

Randomisation is stratified by surgery planned time point (neoadjuvant vs. adjuvant), surgical outcome (R0 vs R1), response to chemotherapy followed by bev (CR/NED vs. PR/SD) and study center. Primary endpoint is PFS per RECIST v1.1. Secondary endpoints are PFS2, quality of life, daily activity, time to next medical intervention, time to next subsequent therapy, safety assessments and OS. So far 35 patients are randomised in the study.

## Results

## Conclusion

2022-RA-939-ESGO

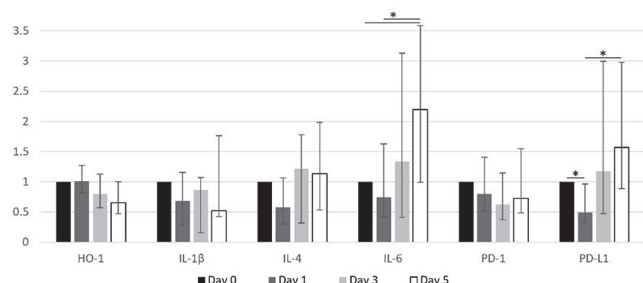
### INFLUENCE OF CANCER AND SURGERY TO IMMUNOSUPPRESSIVE AND PROINFLAMMATORY FACTORS IN OVARIAN CANCER PATIENTS' PBMCs

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**Introduction/Background** Heme-oxygenase 1 (HO-1), programmed cell death protein 1 (PD-1) and its ligand (PD-L1) along with cytokines play an important role in ovarian cancer development. The changes of anti-cancer immunity in post-surgical period and its role in cancer progression are poorly understood. We intended to investigate HO-1, PD-1, PD-L1, immunosuppressive (IL-4) and proinflammatory (IL-1 $\beta$ , IL-6) interleukins expression in peripheral blood mononuclear cells (PBMCs).

**Methodology** The peripheral venous blood samples were collected before and after surgery on the 1st, 3rd and 5th day from 10 controls and 9 ovarian cancer patients (FIGO stage III-IV) for PBMCs isolation with FICOL Paque Premium and targets mRNA expression analysis. RNA extraction and synthesis of cDNA, quantitative real-time PCR assays were performed. Results are presented as median with interquartile range.



**Abstract 2022-RA-939-ESGO Figure 1** Relative mRNA expression of HO-1, IL-1 $\beta$ , IL-4, IL-6, PD-1, PD-L1 genes in PBMCs from ovarian cancer patients on the 1st, 3rd and 5th day after surgery compared to the expression before the treatment. Bar graphs show median value and interquartile range \* $p < 0.05$

**Results** Median age of controls and cancer patients were 59 (26) and 58 (14) years respectively ( $p > 0.05$ ). The mRNA expression of all markers in PBMCs were significantly down-regulated in cancer patients before surgery comparing to

controls ( $p < 0.05$ ). Relative median expression of HO-1, IL-1 $\beta$ , IL-4, IL-6, PD-1 and PD-L1 in controls and cancer patients respectively were 0.97 (0.33) vs 0.66 (0.5), 0.87 (1.95) vs 0.07 (0.16), 0.86 (1.39) vs 0.43 (0.61), 0.98 (1.15) vs 0.03 (0.03), 0.99 (0.94) vs 0.32 (0.50), 1.18 (0.66) vs 0.26 (0.36). Significant post-surgical changes in IL-6 and PD-L1 expression were observed along with not significant fluctuations of other targets expression (figure 1).

**Conclusion** Investigated components of anticancer immunity and immunosuppression mechanisms are affected by cancer and surgical treatment. Therefore, PBMCs are worthy targets for detailed investigation in this field.

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### CEBOC, A SINGLE-ARM PHASE II TRIAL TO EVALUATE THE SAFETY OF CEDIRANIB IN THE PREVENTION OF BOWEL PERFORATION IN PLATINUM RESISTANT OVARIAN CANCER

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**Introduction/Background** Systemic treatment of platinum-resistant advanced ovarian cancers (PROC) utilises cytotoxic chemotherapy and vascular endothelial growth factor receptor (VEGFR) inhibitors. However, patients at risk for malignant bowel obstruction (MBO) are excluded from this efficacious combination due to risk of bowel perforation.

**Methodology** We conducted a Simon's two-stage trial combining oral VEGFR inhibitor cediranib (20 mg/day) with weekly paclitaxel (70 mg/m<sup>2</sup>), in participants with recurrent PROC and clinical and/or radiological features indicating an increased risk of developing MBO. Primary endpoint was number of patients free of grade 3–5 gastrointestinal perforation (GIP) or fistula, from those who received  $\geq 5$  days and  $\leq 18$  weeks cediranib, causally related to cediranib. With 90% power and 5% significance, 24 evaluable patients were required, with 22 free of GIP or fistula to demonstrate safety. Cediranib could start with chemotherapy, or at cycle 2 or 3, once bowel symptoms were CTCAE grade  $\leq 2$ . Previous bevacizumab exposure and prior MBO were permitted. Patients were continued on cediranib maintenance after paclitaxel completion, and optionally proceeded to cediranib plus olaparib (300 mg bd) at disease progression.

**Results** 30 participants were enrolled from March 2018 to February 2021. 90% ECOG 0–1, 97% had symptoms showing risk of bowel obstruction. 1 patient died before any treatment. 12 received paclitaxel only (bowel symptoms didn't improve or deterioration) and subsequently progressed. 17 patients were evaluable for primary endpoint; none developed GIP or fistula. Three cediranib+paclitaxel participants developed bowel obstruction (any grade; including one receiving cediranib+olaparib). Three participants had grade 3+ SAEs causally related to cediranib+/-olaparib (one diarrhoea; one diarrhoea and TIA; one vomiting). Median progression-free survival was 5.4 months (95%CI: 4.18–8.25), and overall survival 15.2 months (95%CI: 8.52–20.5).