Introduction

A randomized trial was conducted to evaluate the efficacy and safety of rucaparib + nivolumab as maintenance treatment following frontline platinum-based chemotherapy for advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Figure 1).

Key eligibility criteria

- Newly diagnosed, stage III/IV, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Completed frontline platinum-based chemotherapy and surgery
- Advanced or recurrent disease (CR or PR on platinum-doublet chemotherapy plus salvage platinum-free therapy, with sufficient tissue available for analysis)
- Disease progression during or within 12 weeks of completing platinum-based chemotherapy, or within 6 months following platinum-free chemotherapy
- No prior treatment for ovarian cancer, including any maintenance treatment, other than frontline platinum regimen

The trial was designed to be flexible and adaptive, allowing for the addition of new subgroups and endpoints based on preliminary results. The study enrolled 250 patients, and the primary endpoint was progression-free survival (PFS) in the intent-to-treat (ITT) population.

Key secondary endpoints included:

- Overall response rate (ORR)
- Time to progression (TTP)
- Time to disease progression
- Safety and tolerability

The trial was conducted in collaboration with multiple centers and institutions, ensuring a diverse and comprehensive patient population.

Key study results:

- Significantly improved PFS in the ITT population (HR 0.49; 95% CI 0.31-0.76)
- Superior ORR in the subgroups characterized by BRCA1 or BRCA2 germline mutations
- Demonstrated encouraging antitumor activity and manageable safety profile

The trial demonstrated the potential for combination therapy in ovarian cancer, highlighting the importance of biomarker-driven treatment strategies. Further research is needed to validate these findings and to optimize treatment algorithms.

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