**BACKGROUND**

Niraparib is a selective poly(ADP-ribose) polymerase (PARP) 1/2 inhibitor approved for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based maintenance treatment for patients with germline mutations in *BRCA1* or *BRCA2*.

**OBJECTIVES**

To determine the long-term tolerability of niraparib, we assessed the incidence of treatment-emergent adverse events (TEAEs) during continued exposure to the drug. We evaluated the risk of blood dyscrasias (including myelodysplastic syndrome (MDS)), which is a known risk of PARP inhibition. We also evaluated the incidence of other key adverse events, as well as the overall tolerability of niraparib.

**METHODS**

**Study Design**

The ENGOT-OV16/NOVA trial was a phase 3, multicenter, randomized, controlled study conducted to evaluate the efficacy and safety of niraparib for the treatment of patients with platinum-sensitive recurrent cancer (Figure 1).

**Patients**

Eligible patients were randomized 2:1 to receive niraparib 300 mg once daily or matched placebo (Figure 2). Of 553 patients enrolled, 203 were assigned to the germline *BRCA1* or *BRCA2* mutation (g*BRCA* mut) cohort and 350 were assigned to the non-g*BRCA* mut cohort.

**RESULTS**

In all cases, the onset of MDS occurred after treatment discontinuation: 70 (50.7%) of patients receiving niraparib and 1 (0.4%) of patients receiving placebo developed MDS after a median follow-up time of 28 months. The incidence of acute myeloid leukemia (AML) was 2 (0.52 cases per 100 patient-years) with niraparib and 0 (0.0 cases per 100 patient-years) with placebo.

**Quality of Life (QoL) measures for patients receiving niraparib showed no QoL impairment, compared with patients receiving placebo.**

**CONCLUSIONS**

These results support the use of long-term use of niraparib for maintenance treatment in patients with recurrent ovarian cancer.

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