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Titolo:	Studio di fase II, randomizzato, in aperto, di non inferiorità, sulla terapia di mantenimento con niraparib dopo 3 o 6 cicli di chemioterapia a base di platino in pazienti con carcinoma ovarico di alto grado in stadio avanzato, sottoposte a citoriduzione completa, positive per HRD ("N-Plus", ENGOT-ov62, NOGGO-ov53)
Patologia:	Carcinoma ovarico
Tipo di studio:	Interventistico
Tipologia:	No profit con grant
Fase:	II
Principali criteri di inclusione:	1. Written informed consent and obtained from the subject prior to performing any protocol-related procedures, including screening evaluations. 2. Female patient, age ≥ 18 years. 3. FIGO Stage III-IV high-grade ovarian cancer (all histological types, except mucinous histology) 4. Complete primary debulked patients (without any macroscopic residuals), confirmed by CT-Scan postoperatively. 5. Patients must have formalin-fixed, paraffin-embedded tumor samples available from the primary cancer for central NGS analysis and must be HRDpositive defined as BRCAmut independent of NOGGO GIS Score OR NOGGO GIS Score >83 independent of BRCA status, based on these results. 6. Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1. 7. Patients must be able to take oral medications. 8. Synchronous and secondary malignancies are allowed if the prognosis of the ovarian cancer is not affected. The investigator must contact the medical monitoring team before enrolling the patient in the clinical trial.
Principali criteri di esclusione:	1. Non-epithelial origin of the ovary, the fallopian tube or the peritoneum (i.e., germ cell tumors) and Ovarian tumors of low malignant potential (e.g., borderline tumors), or mucinous carcinoma of the ovary. 2. Low-grade ovarian, fallopian tube or peritoneal cancer. 3. Has known hypersensitivity to any of the study drugs or any of the excipients of any of the study drugs. 4. Has known hypersensitivity to platin-containing compounds other

	than carboplatin. 5. Patients posttransplant, including previous allogeneic bone marrow transplant. 6. Has undergone interval debulking of the tumor. 7. Has received any anti-cancer therapy for ovarian cancer other than primary surgery. 8. Administration of other simultaneous chemotherapy drugs, any other anti-cancer therapy or anti-neoplastic hormonal therapy, or simultaneous radiotherapy during the trial treatment period (hormonal replacement therapy is permitted as are steroidal antiemetics). 9. Has received prior treatment with a PARP inhibitor or has participated in a trial where any treatment arm included the administration of a PARP inhibitor. 10.Bevacizumab is planned to be given together with first line chemotherapy or as maintenance. 11.Clinically significant cardiovascular disease. 12.History or evidence of brain metastases or spinal cord compression. 13.Known history of MDS or a pre-treatment cytogenetic testing result at risk for a diagnosis of MDS/AML. 14. Current, clinically relevant bowel obstruction at the time of randomization.
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