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| Studientitel | NOGGO S16 (COMPASS) Vergleich der Lebensqualität bei Patientinnen mit platin sensitivem rezidierten Ovarial-, Eileiter- und Bauchfellkarzinom bei der Behandlung mit Trabectedin/PLD oder einer platinbasierten Standardtherapie - eine Kooperation der NOGGO und BNGO | |
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| Wichtigste Einschlusskriterien | <ul style="list-style-type: none"> ➤ Women aged ≥ 18 years ➤ Patients with histologically confirmed diagnosis of epithelial ovarian cancer, primary peritoneal carcinoma or fallopian tube cancer who received ≥ 1 prior chemotherapy ➤ Patients must be eligible for platin-containing therapy; Patient is defined as platin-sensitive when considered for platin-containing therapy by the investigator. The time frame from end of prior therapy until disease progression alone is not pivotal for study participation. Patients without a platin-containing regimen in the previous line who are also eligible for platin-containing regime are also appropriate for participation ➤ Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2 ➤ Adequate baseline organ function as defined as <ul style="list-style-type: none"> • Leucocytes $> 3.0 \times 10^9/l$ • Platelet count $> 100 \times 10^9/l$ • Absolute neutrophil count (ANC) $\geq 1500/mm^3$ • Haemoglobin ≥ 9 g/dl • Alkaline Phosphatase (AP) $\leq 2.5 \times$ ULN (consider hepatic isoenzymes 5 nucleotidase or gamma glutamyl transpeptidase (GGT), if the elevation could be osseous in origin) • Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) $\leq 2.5 \times$ ULN • Creatinine-Clearance ≥ 60 ml/min (MDRD formula or Cockcroft & Gault formula) | |

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| | <ul style="list-style-type: none">• Serum creatinine ≤ 1.5 mg/dl• Creatine phosphokinase (CPK) $\leq 2.5 \times$ ULN• Total bilirubin $<$ ULN ➤ Women of childbearing potential should use contraceptives or abstain from heterosexual activity for the course of the study through 6 months after the last dose of study medication or be surgically sterile.➤ Adequate cardiac function defined as left ventricular ejection fraction (LVEF) $\geq 50\%$ as determined by echocardiogram ➤ <input type="checkbox"/> Patients must provide written informed consent prior to performance of study specific procedures or assessments, and must be willing to comply with treatment and follow up assessments and procedures. |
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