KURZPROTOKOLL
AGO Ovar 2.32

Öffentlicher Titel	Phase III Studie zu Trabectedin/PLD bei Rückfall des Eierstockkrebs
Wissenschaftl. Titel	Trabectedin/PLD versus Fortführung einer platinbasierten Chemotherapie bei Patientinnen mit stabilisierter Erkrankung aber ohne Symptombenefit unter platinbasierter Chemotherapie beim Ovarialkarzinomrezidiv.
Kurztitel	AGO Ovar 2.32
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - Zweitlinie oder höher
Einschlusskriterien	- Females aged >= 18 years at time of signing informed consent form. - Histologically proven diagnosis of cancer of the ovary, the fallopian tube or primary peritoneal cancer. - Measurable or non-measurable disease (according RECIST v1.1) or CA-125 assessable disease (according GCIG criteria) or histologically proven diagnosis of relapse. - Platinum-treatment free interval (TFIp) > 6 months. - Disease stabilization without remission or progression according to RECIST criteria after three cycles of platinum-based chemotherapy. - Symptomatic disease at time of baseline with no symptom benefit and no deterioration after three cycles of platinum-based chemotherapy. - Abdominal/GI symptom scale score > 15 (EORTC QLQ-OV28) after 2 cycles of platinum-based chemotherapy (corresponding to trial baseline). - Patients should have received previously a taxane derivative. - ECOG performance status <= 2. - Life expectancy of at least 12 weeks. - Adequate bone marrow, renal and hepatic function defined as: - 1. Absolute neutrophil count (ANC) >= 1.5 x 10^9/L - 2. Platelet count >= 100 x 10^9/L - 3. Hemoglobin >= 9.0 g/dL - 4. Serum creatinine <=1.5 mg/dL (<= 132.6 micromol/L) or creatinine clearance >= 60 mL/min - 5. Creatine phosphokinase (CPK) <= 2.5 x ULN - 6. Serum aspartate aminotransferase (AST, SGOT) or alanine aminotransferase (ALT, SGPT) <= 2.5 x ULN (<= 5 x ULN in the presence of liver metastases) - 7. Alkaline phosphatase (ALP) <= 2.5 ULN - 8. Serum bilirubin <= ULN - 9. Albumin >= 25 g/l - Participation in an informed consent discussion with the appropriate trial-related health care representative, full understanding of the implications and constraints of the protocol, and provision of written informed consent prior to the commencement of the trial-related procedures. - Geographically accessibility for treatment and follow-up.

	- For women of childbearing potential (WOCBP): agreement to remain abstinent (refrain from heterosexual intercourse) or use a contraceptive method with a failure rate of < 1 percentage per year during the treatment period and for at least six months after administration of the last dose of chemotherapy. A woman is considered to be of childbearing potential if she is postmenarcheal, has not reached a postmenopausal state (12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries, fallopian tubes, and/or uterus). Examples of contraceptive methods with a failure rate of < 1 percentage per year include but are not limited to bilateral tubal ligation and/or occlusion, male sterilization, and intrauterine devices. The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception.
Ausschlusskriterien	- Ovarian tumors of low malignant potential (e.g. borderline tumors). - Non-epithelial ovarian or mixed epithelial/non epithelial tumors (e.g. mixed Müllerian tumors) - Patients with an objective response in terms of a partial or complete remission according to RECIST criteria after three cycles of platinum-based chemotherapy. - Patients who have received previous radiotherapy for ovarian cancer. - History of congestive heart failure (NYHA classification > 2, even if medically controlled). - History of myocardial infarction within the last six months (documented or by electrocardiogram). - History of atrial or ventricular arrhythmias. - Impaired liver function, hyperbilirubinemia, GFR < 60 mL/min, left ventricular ejection fraction < 45 %. - Severe active or uncontrolled infection. - Concurrent severe medical problems unrelated to malignancy, which would significantly limit full compliance with the trial or expose the patient to extreme risk or decreased life expectancy. - Patients with known hypersensitivity to the active substance or their compounds related to trabectedin or PLD and patients with known hypersensitivity to one of active substances or one of their compounds used in platinum-based chemotherapy as described in the Summaries of Medicinal Products. - Patients with potential risks according to contraindication, warnings or interactions of the used chemotherapeutic agents as stated in the SmPCs are not eligible for participation in this trial. - Patients with contraindication regarding CT or MRI (only in case of contrast allergy) are excluded. - Women of childbearing potential (WOCBP) not using highly effective contraceptive methods. - Pregnancy or breast-feeding.
Alter	18 Jahre und älter
Sponsor	AGO Studiengruppe
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03690739 (primäres Register) EudraCT 2017-004934-27