KURZPROTOKOLL
AGO-OVAR 2.21

Öffentlicher Titel	Phase-III Studie zu Gemcitabin vs. pegyliertem liposomalem Doxorubin als second-line Therapie bei Ovarialkarzinom
Wissenschaftl. Titel	Eine prospektive, randomisierte klinische Phase III Studie zur Prüfung von Carboplatin/Gemcitabin/ Bevacizumab vs. Carboplatin/pegyliertes liposomales Doxorubin/ Bevacizumab bei Patientinnen mit platinsensiblen rezidivierendem Ovarialkarzinom.
Kurztitel	AGO-OVAR 2.21
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - Zweitlinie oder höher
Einschlusskriterien	- Histologically confirmed diagnosis of epithelial ovarian carcinoma or fallopian tube carcinoma or primary peritoneal carcinoma - First disease recurrence >6 months after first-line platinum-based chemotherapy - Patients with measurable or non-measurable disease (RECIST v1.1) or CA 125 assessable disease (GCIG criteria) or histological proven diagnosis of relapse - In case of cytoreductive surgery for recurrence, patients must be able to commence cytotoxic chemo-therapy within 8 weeks after cytoreductive surgery - ECOG PS 0-2 - Absolute Neutrophil Count >= 1.5 x 10^9/L; Platelets >= 100 x 10^9/L; Hemoglobin >= 9.5 g/dL - Patients not receiving anticoagulant medication who have an International Normalized Ratio <= 1.5 and an Activated ProThrombin Time <= 1.5 x ULN - Serum bilirubin <= 2 x ULN; Serum transaminases <= 2.5 x ULN (<= 5 x ULN in the presence of liver metastasis) - Serum creatinine < 1.6 mg/dL or creatinine clearance >= 40 mL/min; Glomerular filtration rate > 40 ml/min (estimates based on the Cockroft-Gault or Jelliffe formula); Urine dipstick for proteinuria < 2+. If urine dipstick is >= 2+, 24 hour urine collection must demonstrate <= 1 g of protein in 24 hours - Normal blood pressure or adequately treated and controlled hypertension (systolic BP <= 140 mmHg and/or diastolic BP <= 90 mmHg)
Ausschlusskriterien	- Ovarian tumors of low malignant potential - Malignancies other than ovarian cancer within 5 years prior to randomization - Administration of other simultaneous chemotherapy drugs, any other anticancer therapy or anti-neoplastic hormonal therapy, or simultaneous radiotherapy during the trial treatment period - Any previous radiotherapy to the abdomen or pelvis - Known hypersensitivity to used chemotherapeutic agents in this trial and bevacizumab and its excipients, chinese hamster ovary cell products or other recombinant human or humanised antibodies - Current or recent chronic use of aspirin > 325 mg/day - Surgery (including open biopsy) within 4 weeks prior to anticipated first dose of Bevacizumab - History of VEGF therapy related abdominal fistula or gastrointestinal perforation - Current, clinically relevant bowel obstruction, including sub-occlusive disease, related to underlying disease - Patients with evidence of abdominal free air not explained by paracentesis or recent surgical procedure

- Previous Cerebro-Vascular Accident , Transient Ischaemic Attack or Sub-Arachnoid Haemorrhage
- Prior history of hypertensive crisis or hypertensive encephalopathy
- Clinically significant disease, including: myocardial infarction or unstable angina within <= 6 months of randomization; New York Heart Association (NYHA) >= grade 2 Congestive Heart Failure; poorly controlled cardiac arrhythmia despite medication; peripheral vascular disease grade >= 3
- LVEF defined by ECHO/MUGA below the institutional lower limit of normal
- Significant traumatic injury during 4 weeks prior to randomization
- Current brain metastases or spinal cord compression
- History or evidence upon neurological examination of central nervous system disease
- Non-healing wound, active ulcer or bone fracture
- History or evidence of thrombotic or hemorrhagic disorders within 6 months prior to randomization
- Evidence of bleeding diathesis or significant coagulopathy (in the absence of therapeutic coagulation)
- Fertile woman of childbearing potential not willing to use adequate contraception (oral contraceptives, intrauterine device or barrier method of contraception in conjunction with spermicidal jelly or surgically sterile) for the duration of the trial and at least 6 months afterwards
- Pregnant or lactating women
- Requirement of therapeutic anticoagulation using marcumar, warfarin or PTT-prolonging heparin

Alter	18 Jahre und älter
Sponsor	AGO Studiengruppe
Förderer	AGO Studiengruppe
Registrierung in anderen Studienregistern	EudraCT 2012-004125-24 ClinicalTrials.gov NCT01837251
Therapie	Bevacicumab/Carbo/Gemca vs Bevacicumab/PLD/Gemca