KURZPROTOKOLL
AGO-OVAR 19

Öffentlicher Titel	Studie zur primären radikalen Operation vs. Intervalldebulking Operation bei fortgeschrittenem Ovarialkarzinom
Wissenschaftl. Titel	Eine prospektive randomisierte multizentrische Studie zur primären radikalen Operation vs. Intervalldebulking Operation bei fortgeschrittenem Ovarialkarzinom mit Erweiterung zur Evaluation von Fragilität und Lebensqualität
Kurztitel	AGO-OVAR 19
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	nicht zutreffend
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - Erstlinie

Einschlusskriterien

- suspected or histologically confirmed, newly diagnosed invasive epithelial ovarian cancer FIGO stage IIIB-IV (IV only if resectable metastasis)
- Females aged >= 18 years
- Patients who have given their written informed consent
- Good performance status (ECOG 0/1)
- Good ASA score (1/2)
- Preoperative CA 125/CEA ratio >= 25 (if CA-125 is elevated)*
- If <25 and/or biopsy with non-serous, non-endometroid histology, esophago-gastro-duodenoscopy (EGD) and colonoscopy mandatory to exclude gastrointestinal primary cancer
- Assessment of an experienced surgeon, that based on all available information, the patient can undergo the procedure and the tumor can potentially be completely resected
- Adequate bone marrow function: Absolute neutrophil count (ANC) >= 1.5 x 10^9/L. This ANC cannot have been induced or supported by granulocyte colony stimulating factors.
- Platelet count >= 100 x 10^9/L.
- Renal function: Serum-Creatinine <= 1.5 x institutional upper limit normal (ULN).
- Hepatic function: (a) Bilirubin <= 1.5 x ULN; (b) SGOT <= 3 x ULN; (c) Alkaline phosphatase <= 2.5 x ULN
- Neurologic function: Neuropathy (sensory and motor) less than or equal to CTCAE Grade 1.

Ausschlusskriterien

- Non epithelial ovarian malignancies and borderline tumors
- Secondary invasive neoplasms in the last 5 years (except synchronal endometrial carcinoma FIGO IA G1/2, non melanoma skin cancer, breast cancer T1 N0 M0 G1/2) or with any signs of relapse or activity.
- Recurrent ovarian cancer
- Prior chemotherapy for ovarian cancer or abdominal/pelvic radiotherapy
- Unresectable parenchymal lung metastasis, liver metastasis or bulky lymph-nodes in the mediastinum in CT chest and abdomen/pelvis
- Clinical relevant dysfunctions of blood clotting (including drug induced)
- Any significant medical reasons, age or performance status that will not allow to perform the study procedures (estimation of investigator)
- Pregnancy
- Dementia or significantly altered mental status that would prohibit the understanding and giving of informed consent
- Any reasons interfering with regular follow-up

Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Frankfurt** (Geschlossen) Klinik für Frauenheilkunde und Geburtshilfe Theodor-Stern-Kai 7 60590 Frankfurt am Main Silvia Koss Tel: 069 6301-80429 Fax: 069 6301-83655 silvia.koss@kgu.de **Universitätsklinikum Frankfurt** (Geschlossen) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Silvia Koss Tel: 069 6301-80429 Fax: 069 6301-83655 silvia.koss@kgu.de
Sponsor	AGO Studiengruppe
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02828618