KURZPROTOKOLL
FLOT5

Öffentlicher Titel	Studie zu Chemotherapie vs Chemotherapie mit anschließender Resektion bei Adenokarzinom des Magens oder des ösophagogastrischen Übergangs
Wissenschaftl. Titel	Effect of chemotherapy alone vs. chemotherapy followed by surgical resection on survival and quality of life in patients with limited-metastatic adenocarcinoma of the stomach or esophagogastric junction - a phase III trial of AIO/CAO-V/CAOGI.
Kurztitel	FLOT5
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Einschlusskriterien	- Histologically confirmed limited metastatic gastric or GEJ adenocarcinoma (*) - Medical and technical operability of the primary - Metastatic lesions are resectable or can be controlled by local ablative procedure (central evaluation) - No prior chemotherapy and no prior tumor resection - Female and male patients >= 18 years. Patients in reproductive age must be willing to use adequate contraception during the study and 3 months after the end of the study (appropriate contraception is defined as surgical sterilization (e.g., bilateral tubal ligation, vasectomy), hormonal contraception (implantable, patch, oral), and double-barrier methods (any double combination of: intrauterine device, male or female condom with spermicidal gel, diaphragm, sponge, cervical cap)). Female patients with childbearing potential need to have a negative pregnancy test within 7 days before study start - ECOG (Eastern Cooperative Oncology Group) Performance Status 0 or 1 - Adequate hematological, hepatic and renal function parameters: - a) Leukocytes >= 3000/µl - b) Platelets >= 100,000/µl - c) Serum creatinine <= 1.5 x upper limit of normal, or glomerular filtration rate (GFR) > 40 ml/min - d) Bilirubin <= 1.5 x upper limit of normal - e) AST (aspartate aminotransferase) and ALT (alanine transaminase) <= 3.5 x upper limit of normal - f) Alkaline phosphatase <= 6 x upper limit of normal - Written informed consent of the patient - (*) Definition of the limited metastatic status is: - 1.) Retroperitoneal lymph node metastases (RPLM) (e.g., para-aortal, intra-aorto-caval, parapancreatic or mesenterial lymph nodes) only (Note: in duodenum invading gastric cancer, retropancreatic nodes are not regarded M1) or/and - 2.) at maximum one organ involved with or without RPLM according to the following schema: I. Localized potentially operable peritoneal carcinomatosis: stage P1 according to classification of the "Japanese Research Society for Gastric Cancer" (Clinically visible carcinomatosis of the peritoneum or of the pleura and >P1 peritoneal carcinomatosis are not allowed!) or II. Liver: maximum of 5 metastatic lesions that are potentially resectable or III. Lung: unilateral involvement, potentially resectable or IV. Uni- or bilateral Krukenberg tumors (ovarian met.) in the absence of macroscopic peritoneal carcinomatosis or V. Uni- or bilateral adrenal gland metastases or VI. Extra-abdominal lymph node metastases such as supraclavicular or cervical lymph node involvement or VII. Localized bone involvement (defined as being within one radiation field) or VIII. Other metastatic disease location that is considered limited by the investigator and is confirmed by the review committee
Ausschlusskriterien	- Medical inoperability

- Inability to understand the aims of the study and/or protocol procedures
- Metastatic disease not fulfilling the criteria of limited disease mentioned in the inclusion criteria or non-metastatic stage (cM0)
- Cirrhosis of the liver, pronounced alcohol abuse with anticipated detoxification, severe pulmonary infection with considerable reduction of pulmonary function
- Primary not resectable
- Hypersensitivity to 5-fluorouracil, leucovorin, oxaliplatin, or docetaxel
- Contraindication versus 5-fluorouracil, leucovorin, oxaliplatin, or docetaxel (see specific product information)
- Clinically significant active coronary heart disease, cardiomyopathy or congestive heart failure, NYHA (New York Heart Association) III-IV
- Clinically significant valvular defect
- Past or current history of other malignancies unless curatively treated and without evidence of disease for more than 3 years, except for curatively treated basal cell carcinoma of the skin and in situ carcinoma of the cervix
- Known brain metastases
- Other severe internal disease or acute infection
- Peripheral polyneuropathy > NCI grade II
- Serious hepatic impairment (AST/ALT>3.5xULN, AP>6xULN, bilirubin>1.5xULN; ULN = upper limit of normal)
- Chronic inflammatory bowel disease
- Any other concurrent antineoplastic treatment including irradiation
- Participation in another clinical study
- Pregnancy or lactation

Alter 18 Jahre und älter

Fallzahl 271

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Links	zu den Ein- und Ausschlusskriterien